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NATIONAL HEART TRANSPLANTATION STUDY

VOLUME 4.

LEGAL ISSUES
ETHICAL DILEMMAS

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AN OVERVIEW OF THE LEGAL ISSUES IN HEART TRANSPLANTATION

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A INTRODUCTION

Heart disease is and is likely to remain a catastrophic disease of major proportions--killing or crippling vast numbers of individuals. Coronary heart disease is the leading cause of death in the United States, accounting for two-thirds of all cardiovascular deaths. It is currently estimated that nearly one-third of the deaths from all causes in persons between the ages of 35 and 64 years are due to coronary heart disease, and nearly 40 percent of deaths in white males aged 55 years and over are caused by the disease.

Cardiovascular disease also has extensive economic and social costs. For example, it accounts for more bed days than any other single condition. The total economic cost of cardiovascular diseases is believed to be in excess of $60 billion annually. At present, the only treatment for end-stage cardiac disease is transplantation--the replacement of the patient's damaged heart with a healthy heart from a person who just died of other causes. At present, however, only a limited number of these individuals are viable candidates for cardiac transplantation, because among persons with coronary heart disease there is a critical limitation--sudden onset of death before the individual reaches the hospital. Patients suffering from other less serious heart conditions will probably supply a comparatively smaller percentage of potential transplantation candidates, because they are likely to have other diseased organs that preclude transplantation, or have available to them alternative medical and surgical therapies that offer greater promise of success at a smaller risk. In addition to these problems, a major roadblock to widespread acceptance of

transplantation as a therapeutic technique is the problem or rejection and its treatment through effective immunosuppression. Problems associated with transplantation--infection, rejection, and malignancy --are all related to current methods of immunosuppression. Once the immunosuppression problem is resolved, however, the demand for heart transplantation could rise dramatically.

The major purpose of the legal analysis component of the National Heart Transplantation Study was to identify and discuss those issues regarding heart transplantation that have been formulated in legal terms. The specific objectives of the legal analysis were as follows:

- To determine the implications of special restrictions with regard to <u>who</u> can perform cardiac transplantation;
- to determine the implications of special restrictions with regard to <u>where</u> the procedure can be performed;
- to consider the issues concerning the protection of the donor against premature declaration of death;
- to consider various issues related to the identity of the cardiac donor;
- to consider the legal basis for an individual's claim of a right to a cardiac transplant;
- to interpret the legal viability of strict patient selection criteria, with specific reference to the Civil Rights Act of 1964 and the Age Discrimination Act of 1975;
- to consider the legal implications of de facto exclusion by income level because of out-of-pocket costs for drugs, co-insurance, travel expenses, etc.;
- to determine the legal implications of the Medicare Program for cardiac transplantation; and
- to interpret the legal implications of excluding a specific procedure from Medicare coverage if other procedures of comparable or less favorable cost effectiveness ratios are accepted for Medicare coverage.

As is true with many other areas relevant to organ transplantation, there has been a great deal written about legal issues that are of particular concern to both the legal and medical communities. The public importance of many of these has ebbed and flowed as a result of both changes in medical technology and the mere passage of time. They are, however, still an important concern in terms of law and health policy.

The legal implications of heart transplantation are discussed in Chapters 32, 33, and 34, and material within these chapters is organized by section. Chapter 32 concerns the patient and the patient's entitlement to benefits and consists of four sections. Section 1 discusses patient selection for heart transplantation and the handicapped; Section 2 discusses Title VI and heart transplantation; Section 3 discusses age discrimination in patient selection for heart transplantation; and Section 4 discusses governmental regulation of heart transplantation and the right of privacy. Chapter 33 discusses legal issues surrounding the donor and consists of two sections. Section 1 discusses the source and supply of transplantable hearts, and Section 2 discusses protection of the privacy of organ and tissue donors. Chapter 34 discusses legal issues surrounding the provider and consists of four major sections. Section 1 discusses due process and equal protection considerations in heart transplantation; Section 2 discusses governmental regulation of heart transplantation and transplant providers; Section 3 discusses the antitrust laws and their implications for the regulation of heart transplantation; and

Section 4 discusses special malpractice issues in heart transplantation. The material that follows will provide a brief overview of the contents of each chapter and the sections within chapters.

B. THE PATIENT AND ENTITLEMENTS TO BENEFITS

Although many aspects of heart transplantation are still considered to be experimental, a consistent pattern has emerged with respect to the process of patient selection. In general, potential transplant candidates are assessed for treatment suitability by a group that includes a cardiologist, a social worker and a cardiac surgeon, all of whom have significant responsibility for direct patient care. Typically the group accepts a number of patients roughly equal to the number of transplants that can be performed at any given period. While they are not labelled as such, the program eligibility standards seem to be that: (1) the patient have a critical medical need for the transplant, (2) there be no alternate medical or surgical means that allow greater survival, and (3) the procedure have a reasonable chance of successful outcome given the current state of transplant technology.

Specifically, in order to be considered for transplantation a patient must have a New York Heart Association Class 4 cardiac disability (essentially a bed-to-chair existence) and/or have an estimated life expectancy of less than six months. In addition, the patient must have no medical contraindications to treatment, such as a recent history of pulmonary embolism, and other major organ systems also must be free from disease and infection.

Heart transplantation specialists have also singled out several psychosocial characteristics as bearing on the patient's viability. According to current practice, the patient should have a strong "will to live" as well as the ability to endure the stress and tension caused by the pain of treatment and the need for a serious adjustment in lifestyle during the treatment and rehabilitation periods. Transplantation programs have translated these general psychosocial requirements into several specific patient selection criteria. To assure the proper mental attitude, and to facilitate the patient rehabilitation process, the patient must have a stable and rewarding family or vocational environment to return to following the transplant procedure. In addition, the patient may be excluded if he or she has experienced a history of alcoholism, job instability, or anti-social behavior. Finally, when patients are found to be otherwise suitable for transplantation, they are subjected to a variety of blood and histocompatibility tests.

The material in Chapter 32 specifically focuses on patient selection and the legal issues that such selection may raise. The major focus of this inquiry is on discrimination in the process of patient selection; specifically, patterns of patient selection and patient selection processes that may discriminate against the handicapped, against ethnic or racial groups, or against groups of individuals based on age.

1. PATIENT SELECTION FOR HEART TRANSPLANATATION AND THE HANDICAPPED

Current patient selection criteria and processes may be subject to attack under the federal handicapped discrimination law

because they may place barriers between transplantation treatment and the handicapped individual. Much like employment and college applicant screening, the discretionary nature of the patient selection and screening process may be affected by the screener's unconscious biases against, or unfounded perceptions, of handicapped individuals. Discriminatory attitudes toward the handicapped, much like attitudes toward racial or ethnic minorities, remain embedded in our culture. However, unlike race or alienage, a handicap--the trait that gives rise to the individual's legally protected status--may actually be perceived as a medical contraindication to treatment or as a indicator of emotional or mental instability, even though it may not affect the handicapped individual's ability to benefit from treatment. In addition, handicapped individuals are sometimes considered less able to make rewarding contributions to the community through social interaction. This factor may be crucial in the allocation of scarce medical resources, because those individuals considered most likely to make contributions to society may be consciously or unconsciously favored for selection as transplant recipients.

The use of ostensibly evenhanded patient selection criteria may also weigh against the handicapped in several other ways. First, some disabilities--correctly or incorrectly--are judged to be medical contraindications to treatment. A severe diabetic, for instance, would probably not be considered as a candidate for heart transplantation. Second, resource rationing and research considerations often dictate that decisionmakers choose candidates who are least likely to suffer debilitating complications. Physicians in a new field may

often be playing the medical odds--and may be disinclined to choose a person for treatment who has any history of medical or psychological debilitation. Third, some handicaps may limit, or be perceived as limiting, the individual's ability to adhere to a strict regimen during post-transplantation rehabilitation. The heart transplant recipient, for instance, must follow a rigorous post operative treatment regimen consisting of drug therapy and significantly altered lifestyle. An applicant with a limited intellectual capacity may be excluded because of doubts about whether that individual could adequately maintain the necessary medication schedule. Finally, the use of exclusionary criteria may reflect stereotyped assumptions about the emotional or mental characteristics of the handicapped.

Section 504 of the Rehabilitation Act of 1973 prohibits discrimination on the basis of handicap in any program or activity receiving federal financial assistance. The operative language of Section 504 provides:

> No otherwise qualified handicapped individual in the United States, as defined in Section 706(7) of this Title, shall, solely by reason of his handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving federal financial assistance or under any program or activity conducted by any executive agency or by the United States Postal Service.

While the statute itself amounts to a broad extension of civil rights protection to the handicapped, the bare language of the statutes provides little guidance to its application in specific fact situations. To ameliorate this difficulty, the Secretary of Health, Education and Welfare issued regulations in 1979 to enforce the

congressional mandate of providing equal opportunity to the handicapped. These regulations address some, but not all areas of controversy, under Section 504. Section 1 of Chapter 32 discusses several of the most pressing questions concerning Section's 504 applicability to patient selection for heart transplantation, drawing on both the regulations and case law dealing with Section 504 in other settings.

The questions that arise (and are addressed in section 1) generally center on the scope and substance of the Rehabilitation Act of 1973. For example:

1. What is the scope of the Rehabilitation Act?
2. Is a heart transplantation program a "program or activity" under the statute?
3. Must the heart transplantation program itself receive federal funds, or is it sufficient that the hospital receives them?
4. Are experimental procedures within, and thus subject to the anti-discrimination laws?
5. What the term "qualified handicapped individual" mean in a transplantation setting?
6. What limitations does the Rehabilitation Act place on the use of patient selection criteria?
7. What types of patient selection practices may violate the Act?

Because the regulations interpreting Section 504 are still relatively new, it is difficult to arrive at anything more than a tentative outline of the responsibilities and rights that the Rehabilitation Act imposes. This is particularly true when this

relatively untested law is applied in the transplantation setting, one at the leading edge of medical science and technology.

Although it arrives unanticipated, we must still face up to the possibility of discrimination in the allocation of health care resources. We live in an era in which medicine holds the promise of effective treatment for many types of catastrophic diseases--treatments that are and will remain scarce due to fiscal and resource shortages. As the cost and complexity of medical care increase, physicians will be faced with the necessity of allocating scarce medical resources. Whether through assessment of treatment suitability, by lottery, or by chance, these allocations must stay within the confines of the applicable anti-discrimination laws.

2. TITLE VI AND HEART TRANSPLANTATION: DISCRIMINATION IN PATIENT SELECTION

Title VI of the Civil Rights Act of 1964 prohibits discrimination on the basis of race, color, or national origin in federally assisted programs. Section 601 of that Act provides that:

> No person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving financial assistance.

While Title VI was enacted primarily to prohibit segregation in publicly funded schools, it applies equally to all recipients of federal funds, including institutions that provide health care. Because virtually all hospitals with transplant programs accept some form of federal financial assistance, Title VI has important implications for patient selection practices for heart transplantation.

The potential impact of Title VI on patient selection for heart transplantation is difficult to assess, because to date, the Title VI enforcement program has not brought substantive issues of discrimination to the fore, even in the most common areas of health care. However, due to the increasing concern over rising health care costs and the use of sophisticated health care technology, government scrutiny of all facets of health care and health care spending is likely to increase. It is in this context that the issue of discrimination and the selection of patients for transplantation must be considered, because the regulatory and allocative decisions that are currently being made with respect to heart transplantation may adversely affect racial and ethnic minorities.

The nature and extent of the problem of racially based inequities in heart transplantation programs is difficult to define precisely or to specify. However, substantial disparities may exist in the receipt of heart transplant procedures by race and ethnicity. In other areas of health care, the evidence indicates that racial and ethnic minorities do not have equal access to medical services. It is likely, particularly in light of the emphasis on selectivity in the heart tranplantation setting, that this problem is or will be exacerbated in the process of selecting patients for heart transplantation. The important question is whether any part of the disparity arises out of discrimination in the legal sense of the term, and if so, whether and when such discrimination can be legally attributable to the patient selection procedures of the government or specific health care facilities. While aspects of patient selection

may raise Title VI issues, many cannot be definitely settled because of the difficulty of determining both the content and scope of Title VI as it applies in this specialized area of health care.

The content issues concern the affect of Title VI on patient selection practices. They include the choice of patient selection criteria, application of those criteria to the heart transplant candidate, and the impact of a range of environmental and sociocultural factors on the representation of racial and ethnic minorities in the transplant recipient population. The scope issues involve the persons and institutions to whom the statute applies. Even a cursory examination of the complicated arrangements through which patients are referred to heart transplantation programs and chosen for treatments suggests a number of difficult issues that are only briefly discussed in Section 2. These include:

1. Who is responsible if a private physician makes discriminatory referrals to a transplant program?

2. May a federal agency write and enforce regulations that would violate Title VI if written and imposed at the transplant program level?

3. Is the transplant facility open to charges of discrimination if it utilizes discriminatory patient selection criteria that are promulgated by a federal agency?

The potential merit of many claims of discrimination in patient selection and referral rest on resolution of these scope and content issues. Yet these issues cannot be definitively addressed because they, in turn, reflect further uncertainties in two central areas in Title VI law. These are: (1) whether a discriminatory

affects or intents standard is appropriate for Title VI litigation and enforcement, and (2) the meanings of "federal financial assistance" and "recipient" as they arise under Title VI.

The applicable standards substantially impact on the content issues because differential access to heart transplant programs by racial and ethnic groups may arise out of facially neutral practices actionable, if at all, only under the affects test. The second uncertainty--the meanings of "federal financial assistance" and "recipient"--is important to the scope issues because only health care providers who receive federal financial assistance, and are thus "recipients," are subject to Title VI.

Transplant facilities, referring physicians, and government agencies such as the Health Care Financing Administration each may take actions that can significantly affect the access of racial and ethnic minorities to health care resources. Title VI of the Civil Rights Act of 1964 may have implications for these actions with respect to patient selection for heart transplantation. Although the unsettled nature of Title VI law in this area precludes the formation of definitive conclusions, it appears that Title VI may impose limitations on: (1) the permissible range of patient selection criteria, (2) physician and hospital referral practices, and (3) federal agency standard setting for provider inclusion in Medicare heart transplantation reimbursement plans.

As we indicate in the body of this section, the choice and use of patient selection criteria may be circumscribed under Title VI if they result in discrimination against racial or ethnic minorities

even if they were not intended to have that effect. These limits may apply to both the transplant facility and the referring physician. In addition, it may be advisable for the Health Care Financing Administration to assure that any standards for patient selection it may impose on transplant facilities, as a condition of participation in a Medicare reimbursement program for heart transplantation, do not conflict with the mandates of Title VI in order to avoid the creation of possible non-compliance issues for the transplant facility, if not for health care financing administration itself.

3. AGE DISCRIMINATION IN PATIENT SELECTION FOR HEART TRANSPLANT

When the Health Care Financing Administration solicited applications from hospitals and medical centers to participate in the National Heart Transplantation Study, it included procedures and criteria to be used for selecting the institutions to participate in the study. The second of four criteria required that applicant institutions have adequate patient selection criteria, evidenced by (among others) criteria that give consideration to those factors that are recognized as exerting adverse influence on patient outcome following heart transplantation. Such "strongly adverse factors" include:

> 1. Advancing age--e.g., beyond the age (normally about 50) at which the individual begins to have a diminished capacity to withstand post operative complications.

Section 3 examines, through the lens of the Age Discrimination Act of 1975, the legal viability of "advancing age" as a strongly adverse factor in the selection of patients for heart transplantation.

The basic structure of the Age Discrimination Act is simple. The Act prohibits discrimination on the basis of age in all federally assisted programs and activities, and then exludes from coverage those programs or activities "established under authority of any law" employing age criteria to condition benefits or participation. In addition, the statute contains several broadly worded "reasonableness" exceptions to the general prohibition. Finally, the Act requires each federal agency or department to issue implementing regulations. Enforcement of the Age Discrimination Act is to be through governmental agencies and departments and, following the 1978 amendments, by private individuals through the courts.

The Age Discrimination Act is expressly modeled on Title VI of the Civil Rights Act of 1964, which prohibits discrimination on the basis of race, color, or national origin in federally assisted programs. The prohibiting language of the Age Discrimination Act is nearly identical to that contained in Title VI, and to that in Title IX of the Education Act of 1972, and Section 504 of the Rehabilitation Act of 1973. In adding age to the list of protected characteristics (i.e., race, color, national origin, and handicap), Congress stressed that the Age Discrimination Act was intended to protect all persons of all ages, but it is clear that discrimination against the elderly was their primary concern.

Although enacted in 1975, the Age Discrimination Act has only very recently been fully implemented and thus there is little case law interpreting its provisions. Depending upon these interpretations, the Age Discrimination Act may require major changes in the ways in

which both public and private organizations conduct their activities. For example, the Department of Health, Education, and Welfare originally estimated that the Age Discrimination Act would apply to nearly 100,000 public and private entities that receive federal financial assistance, including hospitals and schools. The promise of its impact, however, may never come to pass--while the Age Discrimination Act was based on an analogy to the prohibition of race and sex discrimination, the prohibition was subject to such broad exclusions and exceptions that they may have deprived the Act of its intended effect.

The Congressional formula in the Age Discrimination Act for proscribing the use of age distinctions is based to a large extent on a report on age discrimination prepared by the U.S. Civil Rights Commission. The results of the Commission Report found their way into the language of the Age Discrimination Act and the regulations implementing the provisions of the statute. The Commission Report investigated the nature and extent of age discrimination in a variety of federal programs and federally assisted activities. It began by setting down an extremely broad definition of age discrimination--"any act of failure to act, or any law or policy that adversely affects an individual on the basis of age."

Given the constraints imposed by criticisms of its definition of age discrimination, the Commission Report concluded that of all the programs and activities it had studied: (1) age discrimination was widespread, (2) persons over the age of 65 were consistently adversely affected by the use of age distinctions, and (3) the administrative

justifications for the use of age distinctions were not acceptable. The Commission Report recommended that, in order to expand the scope of the Age Discrimination Act, the statute's statement of purpose be amended to prohibit all age discrimination, not just that which was "unreasonable," and that the "reasonableness" exceptions and the "any law" exclusion be replaced with two other very narrow exceptions. Apparently on the basis of the Commission Report recommendations, Congress amended the Age Discrimination Act to delete the word "unreasonable" from the statement of purpose, but left intact the reasonableness standards contained in the exceptions. The task of reconciling these differences was left to the Department of Health, Education and Welfare in the formulation of government-wide regulations for the implementation of the provisions of the Age Discrimination Act.

The overview of the regulations states the general rule that "separate or different treatment that deny or limit service from or participation in a program receiving federal financial assistance will be prohibited. . . ." More specific guidance about this prohibition is provided in the Rules Against Age Discrimination:

> The rules stated in this section are limited by the exceptions contained in Sections 90.14 and 90.15 of these regulations.
>
> (a) General Rule: No person in the United States shall on the basis of age, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving federal financial assistance.
>
> (b) Specific Rules: A recipient may not, in any program or activity receiving federal financial assistance, directly or through contractual, licensing or other

> arrangements, use age distinctions or take any other actions which have the effect, on the basis of age, of: (1) excluding individuals from, denying them the benefits of, or subjecting them to discrimination under, a program or activity receiving federal financial assistance, or (2) denying or limiting individuals in their opportunity to participate in any program or activity receiving federal financial assistance.

The statement of the broad scope of coverage of the Age Discrimination Act contained in the overview of the regulations is considerably reduced by later regulatory provisions interpreting the statutory exceptions and the exemptions dealing with employment practice, affirmative action, and special benefit programs.

With the caution that there is a woeful lack of law supporting any specific interpretation of the Age Discrimination Act, several tentative conclusions can be made. First, discrimination on the basis on age is not viewed with the same degree of alarm as discrimination on the basis of race, sex, or religion. In general, the use of age distinctions will be subject to fewer legal restrictions than other forms of discrimination. Second, regardless of the ultimate determination of the meaning of "any law," the use of a strict age criterion in patient selection for heart transplantation will be excluded from the Age Discrimination Act's general prohibition against age discrimination. Third, because the use of a strict age criterion is not "necessary" to the normal operation of a heart transplant program, its use would not meet the requirements of the "normal operation" exception of the Age Discrimination Act. Finally, if the relationship between age and survivability is demonstrably strong, the

use of a strict age criteria will be exempt from the Age Discrimination Act under the "statutory objective" exception.

4. GOVERNMENTAL REGULATION OF HEART TRANSPLANTATION AND THE RIGHT OF PRIVACY

Many have argued that individuals have a right to choose to undergo various forms of medical treatment in accordance with their own best judgment and wishes. In constitutional analysis, the ability of the individual to decide what experiences to undergo is commonly referred to as the "right of personal autonomy," one aspect of the constitutionally based right to privacy. The central theme of this right is the individual's freedom to make personal decisions, so long as they do not adversely affect others. Its philosophical underpinnings are credited variously to Locke, Rousseau, and the authors of the Declaration of Independence.

The central question addressed in Section 4 of Chapter 32 is whether the Supreme Court's doctrine of personal autonomy could encompass an individual's independent decision, with the advice of a physician, to undergo a medical therapy or procedure such as heart transplantation. In claiming this right, the individual would be claiming the right to be free from unwarranted government intervention and regulation in his or her treatment decision, rather than the right to receive resources sufficient to provide the patient active assistance to obtain the treatment. Like the right to decide whether to bear a child, any constitutional right to choose a method of treatment would be a right to be free from governmental restriction, and not an entitlement to public resources.

If the right to decide to undergo medical treatment was recognized as fundamental, all government regulation of health care decisionmaking would not be disallowed. No "right" is absolute; all are subject to limitations when their exercise conflicts with other sufficiently weighty interests. In essence, the right would mean that absent government restriction, the individual would be free to effectuate his or her decision to undergo a particular form of treatment, and that only certain government restrictions would be valid. Thus if recognized, a right to choose a method of treatment must yield to other overriding public interests, just as the woman's decision to bear a child can be circumscribed when state interest in the life of the fetus and maternal health become sufficiently strong.

While the exercise of such a right can be circumscribed, the significance of a right lies in the test that is applied to determine the validity of government actions restricting that right. In other words, the importance of a right lies in the degree of harm to other state concerns that must exist before that right can be limited. The government has broad powers to curtail individual freedom of action in order to promote legitimate state concerns, except where there is a "fundamental right" involved. Since the Supreme Court's rejection of "substantive due process" protection of economic and property rights in the mid- to late-1930s, the Court will actively protect only <u>fundamental</u> constitutional rights from unduly burdensome action. Fundamental rights are those found within the text of the Constitution or its amendments, or those that reflect values found by the Court to

be fundamental to freedom in American society, but are not found within the text of the Constitution itself. The most significant of the non-textual fundamental rights recognized by the Supreme Court are the right of freedom of association, the right of privacy, and the right to vote.

The significance of a fundamental right lies in the level of justification that the state must assert in order to circumscribe it. When a governmental enactment is challenged, it is generally presumed to be valid. Unless a fundamental right is involved, the challenger has the burden of establishing that the law has no rational relation to a legitimate end of government, such as improving health, safety, welfare, or morals. As long as there is any conceivable basis for finding such a rational relationship, the law will be upheld. Only where a law is a totally arbitrary depravation of liberty will it violate the due process clauses of the Fifth or Fourteenth Amendment to the Constitution. This test of validity of governmental action is commonly termed the "rational basis test."

Governmental impingement on fundamental rights, on the other hand, must satisfy a higher standard of validity. First, the government, rather than the challenger, has the burden of showing the need for the law. Second, only those needs that are "substantial," "compelling," or "overriding," will be upheld. Third, the law must be carefully tailored by the government to limit the constitutional right only to the extent necessary to effectuate the government's overriding interest. In short, impingement of a fundamental constitutional right initiates a stricter scrutiny, both of the government's goals and the

means by which it seeks to accomplish them. This more rigid standard is commonly referred to as the "strict scrutiny test."

Governmentally imposed burdens on individuals that pass judicial review under the rational basis test often will not meet the more rigorous requirements of the strict scrutiny test. Thus, anchoring the decision to choose a particular method of treatment to a fundamental right in the Constitution is of great significance to attempts to regulate health care delivery. Without a constitutional foothold, a legislative determination that an individual's choice of treatment imposes burdens on other persons that justify restrictions will be readily accepted by the courts, and could leave the government with far more latitude to regulate the availability and performance of certain surgical and medical techniques, such as heart transplantation.

However, if freedom to choose a particular method of treatment is considered a fundamental right, then state restrictions on that freedom will be less easily imposed because they will have meet a heavier burden of justification (one that, in many cases, may not be demonstrable). Restrictions may still be imposed, but only where there is a clear necessity for them, with all doubts resolved in favor of the individual's right to choose treatment. Clearly, there are costs to the government here in terms of limitations on its ability to regulate in areas in which it may have some interest. But these costs would be justified on the ground that they would be less onerous than the loss of the individual's personal autonomy in an area as vital as health care.

Given the high value that American society has placed on both personal autonomy and bodily integrity, it is not surprising that a constitutional right to choose to undergo particular forms of medical treatment is now being urged upon the courts. While the Supreme Court has never directly faced the question, the constitutional doctrine that it has developed under the label of the right to privacy could furnish a foothold for such a right.

C. LEGAL ISSUES SURROUNDING THE DONOR

The increasing success of clinical heart transplantation in the United States and the rest of the world enhances the potential for using transplantation as a routine method of treatment. Continued progress, however, is limited by two major constraining factors--a lack of effective immunosuppressive regimens to overcome rejection of the transplanted heart, and the scarcity of donor hearts for transplantation. Chapter 33 discusses three major topics of interest to an analysis of the legal implications surrounding organ donors. Section 1 discusses legal issues surrounding the source and supply of transplantable hearts, including questions arising under the Uniform Anatomical Gift Act and alternatives to reliance on voluntary donation. Section 2 discusses protections surrounding the privacy of organ and tissue donors, and Section 3 contains a synopsis of the President's Commission Report examining issues in the declaration of death and protecting the organ donor from premature declaration of death.

1. THE SOURCE AND SUPPLY OF TRANSPLANTABLE ORGANS

The material in this section of Chapter 33 briefly discusses the question of the effect of Medicare reimbursement on donor organ availability procurement. It also addresses the more general issue of organ shortage and resource allocation. Much of the material in this section of the chapter is drawn from the experience of the end-stage renal disease program, which provides a clear picture of the effect of full reimbursement on the demand for medical resources and donor organs. Section 2 discusses the legal implications and consequences of alternative methods of regulating the source and supply of donor organs. Although focus of the section is on the role of the Uniform Anatomical Gift Act, the material also briefly considers the use of unclaimed body statutes and autopsy laws, compulsory removal proposals, and procedures for the sale of organs.

It is apparent that advances in transplant technology are driving the demand for transplantable organs beyond the capacity of the current supply system. Continued reliance on ad hoc pleas and donations, and uncoordinated organ procurement procedures simply does not meet the current needs for organs and will surely will not meet the increased needs that are just over the medical horizon. Careful thinking about the source and supply of transplantable organs leads one to consider two separate aspects of the problem--efforts within the existing framework of the Uniform Anatomical Gift Act, and alternatives to reliance on donation.

In theory, the Uniform Anatomical Gift Act provides an adequate legal vehicle through which to procure organs for

transplantation. A great deal of time, effort, and study went into its preparation in order to ensure that significant legal impediments would be overcome. In practice, however, donation remains an unsatisfactory solution to a pressing problem. There is considerable evidence that important legal provisions of the Uniform Anatomical Gift Act are largely ignored by those involved in organ procurement. Although the Uniform Anatomical Gift Act explicitly recognizes donor documentation (i.e., a donor card) as sufficient legal evidence of an individual's donative intent (and extends blanket immunity to physicians and other medical personnel acting in "good faith" in regard to organ procurement), the majority of medical institutions do not permit organ removal without the consent of next-of-kin. While the underlying philosophy of the Uniform Anatomical Gift Act is to facilitate the expression of an individual's intent to donate, the reality of the situation is that such intentions are not carried out unless and until a family member or relative consents.

It is apparent that the medical community feels that the provisions of the Uniform Anatomical Gift Act provide them sufficient legal protection from aggrieved next-of-kin. The important question here is whether stronger legal protections are needed to assuage physicians fears of liability, and if so, what guarantees would have to be given to bring their practices into line with the theory of the law regarding organ procurement. It is not at all apparent that additional legal protection is needed to encourage organ donation and procurement under the Uniform Anatomical Gift Act. It seems clear that fundamental changes in attitudes must precede any long-term and

stable increase in the number of transplantable organs made available through voluntary donation under the Uniform Anatomical Gift Act.

We have only recently seen the first of a number of likely legislative solutions to the problem of organ donation and procurement. For instance, as a result of a series of hearings before the Investigations and Oversight Subcommittee of the Science and Technology Committee, Albert Gore, Jr. (D-Tenn) has introduced legislation to implement a nationwide strategy to overcome the problems of organ procurement discussed above. The legislation is intended to achieve three primary goals: (1) to increase voluntary donation of organs, (2) to improve coordination of organ procurement and distribution, and (3) to ensure equitable and timely access to lifesaving and medically effective technologies. To meet these goals, the legislation calls for: (1) formation of a national center for human organ acquisition, (2) development of a program to promote organ donation, (3) development of an aggressive organ acquisition program, (4) re-establishment of the National Center for Health Care Technology, and (5) restriction of organ transplantation to designated regional centers.

Because of some degree of skepticism about the ultimate ability of society to provide a sufficient number of organs through donations, several other alternatives to the Uniform Anatomical Gift Act have been imposed. Any proposal to go beyond voluntary donation, such as compulsory removal, a market system, or "opting out," will inevitably raise complex legal issues that will have to be resolved either legislatively or through the courts. If carefully tailored to

avoid infringing on fundamental constitutional rights, none of these alternatives would be inherently illegal.

However, as is the case with reforms or revisions in the Uniform Anatomical Gift Act, the important issues do not appear to involve fundamental legal questions. Rather, proponents of any alternative must be prepared to deal with fundamental ethical and moral objections that would surely arise. Such objections may be the expression of deeply held values and attitudes about the treatment of both living and the dead (regardless of how those terms are legally, medically, or socially defined), and may only manifest themselves in legal challenges or be cloaked in legal terminology as a means of accomplishing an end. Defending the legal validity of any such alternative is only a relatively minor technical problem, requiring careful legal research and legislative drafting. The more significant undertaking, however, will be to reconcile attitudinal and sociocultural sentiment with the implementation of such proposals.

2. PROTECTING THE PRIVACY OF ORGAN AND TISSUE DONORS

In the past decade, patient confidentiality and privacy issues have generated a great deal of discussion in medical, ethical, and legal circles. Discussions often center on the tension between society's interest in protecting the confidentiality of medical records and its countervailing interest in allowing use of patient information to promote public health. Seldom, however, are the interests in patient confidentiality directly pitted against the life and health of another human being, for seldom do the physical characteristics and make-up of an anonymous, unrelated individual bear

directly upon the life chances of another. However, the resurgent interest in transplantation and the increased need for donor organs and tissues have brought these competing interests into direct confrontation.

Tissue typing information is increasingly stored in medical records as an incident of assessment of individuals as potential organ or tissue donors. Due to advances in electronic data processing, it is now economically and logistically feasible to organize this decentralized tissue into central "donor information banks," often without having to approach the subject for consent to collect the information. While this type of centralized data collection may be a boon to certain types of transplantation, because it allows rapid searches for compatible tissue donors, it also may pose new challenges to our conceptions of confidentiality and medicine. For example, it is often very difficult to locate compatible bone marrow, platelets, and rare types of blood for persons in need of transplants and infusions. Those needing the services understandably place great value on obtaining information about persons with compatible tissue types. If persons in need of blood, marrow, or platelets could gain access to individually identifiable tissue type information, then tissue typed individuals could find themselves exposed to personalized and potentially coercive pleas for donation.

Even if health care providers have a policy of protecting this type of information, unauthorized access could occur in several ways. First, persons could use various types of computer tapping to break into electronically stored tissue type information banks.

Second, health care personnel with access to the files could improperly divulge information. Finally, individuals might seek access to centrally stored medical information through appropriate legal channels. Given the rapid adoption of data processing, practices such as this would be increasingly commonplace. The question that must be answered is whether we, as a society, feel that the ease and convenience of allowing nonconsensual use of previously gathered medical information for purposes that do not medically benefit the subject, outweigh the infringement on personal privacy and confidentiality interests.

Many other questions relating to confidentiality of tissue type information can--and perhaps will--be litigated in the future. These include: (1) the amenability of other state laws, including freedom of information acts, to interpretations that would extend medical confidentiality requirements to the records of tissue and organ donors; (2) the type and level of sanction that could be applied under existing statutes to institutions that release such information; (3) whether a tissue typed individual whose identity or medical information was disseminated without his or her consent (or the consent of the next-of-kin if the patient is dead or near death) can bring an action against a public or private health care institution or those gaining access to the information to recover monetary damages under legal theories such as breach of contract, invasion of privacy, or negligent infliction of emotional distress; (4) whether hospitals can relay without consent information about the potential donors identity, medical condition, or tissue type to independent organ

procurement agencies without running afoul of state statutes controlling access to information contained in medical records; (5) what type of information the hospital may legally give to the donee about the donor once the transplant occurs; and (6) whether a physician could refuse to release the medical records or identity of a donor, where, for example, the recipient of the tissue or organ was bringing a civil action for negligent implantation of a defective organ or tissue.

The uncertain legal status of potential and actual donor information may necessitate enactment or reconsideration of confidentiality guidelines. However, those guidelines, whether implemented by an institution or a legislature, must accommodate not only the rights of patients to informational privacy but also the needs of health care providers for ready access to information necessary for treatment. Another factor that must be weighed is cost; protection of HLA and other donor specific information will entail expenditures of both time and money. While we as a society feel that psychiatric records may demand stringent safeguards, it may not be cost effective to protect tissue type information, even though from an ethical standpoint the patient may be equally entitled to have it protected. The questions we must ask ourselves include: What information should we protect? From whom? At what price? How comprehensive should such regulation be? Where do we strike the balance in each case?

At a minimum, persons trained in handling transplant related medical data must be sensitized to the ethical and legal

considerations inherent in their work. It may also be advisable for health care personnel to consider obtaining explicit prior consent from donors in order to use HLA data for specified purposes. In addition, perhaps the entire data collection and dissemination system should be carefully monitored to correct potential abuses.

3. DECLARATION OF DEATH: A SYNOPSIS OF THE PRESIDENT'S COMMISSIONED REPORT

In November of 1978 the United States Congress authorized the creation of a presidential commission with continuing responsibility to study and report on the ethical and legal implications of a number of issues in medicine and research. The first issue posed in the Commission's congressional mandate was the question of whether the law ought to recognize new means for establishing that human death had occurred. Although apparently straightforward, this question was seen as troublesome for several reasons. First, in many cases, ventilators and other associated medical technologies are capable of maintaining heartbeat and respiration in dead bodies--those having sustained total and irreversible cessation of all brain functions. Thus, the beating heart no longer plays a central role in differentiating the living from the dead. Second, confusion arose because the same medical technology not only kept heart and lungs functioning in some who had irretrievably lost all brain functions, but also sustained other less severely injured patients. Inexact medical and legal descriptions of these two categories led to a blurring of the important distinction between patients who were already dead, and those who were simply in the process of dying.

The study of the ethical and legal implications of the matter of defining death, as it was stated in the congressional mandate, was also the first report that the President's Commission completed. The study began with hearings and written testimony in May and June of 1980 on the medical, ethical, religious, legal, and public policy aspects of the determination of death. The Commission also sponsored empirical investigations in the various outcomes of respirator support for patients in coma of both traumatic and non-traumatic origin, in order to gain some understanding of how frequently determinations of death by traditional measures of heartbeat and respiration were made more difficult by the medical application of artificial means of life support. The results of this empirical study highlighted the importance of addressing the ethical implications of decisions to cease treatment, since most "heart cases" faced by clinicians involve patients who were failing to recover, not those who ceased having a brain function.

In performing its mandate, the President's Commission reached several central conclusions. First, recent developments in medical treatment have necessitated restatement of the standards traditionally recognized for determining that death has occurred. Second, such a re-statement should preferably be a matter of statutory law. Third, such a statute should remain a matter for state law, with federal action, at this time being limited to areas under current federal jurisdiction. Fourth, the statutory law ought to be uniform among the several states. Fifth, the "definition of death" contained in the statute should address general physiological standards rather than

medical criteria and tests, which will change with advances in biomedical knowledge and refinements in medical techniques. Sixth, death is a unitary phenomenon that can be accurately demonstrated either on the traditional grounds of irreversible cessation of heart and lung functions, or on the basis of irreversible loss of all functions of the entire brain. And seventh, any statutory "definition" should be kept separate and distinct from provisions governing the donation of cadaver organs and from any legal rules on decisions to terminate life sustaining treatment.

D. LEGAL ISSUES SURROUNDING THE PROVIDER

Volume 34 discusses legal issues surrounding the provider and consists of four major sections. Section 1 describes due process and equal protection considerations in heart transplantation as they relate to the provision of health care services. Section 2 discusses government regulation of heart transplantation and considers to what extent regulation may influence the practice of transplant physicians. Section 3 discusses the antitrust implications of the regulation of heart transplantation and discusses how the antitrust laws may be used to frustrate attempts to regulate or limit access to transplant procedures. Finally, Section 4 discusses special malpractice issues that are of concern in the transplant context, including potential liability for actions taken with respect to the donor and potential liability issues that may affect actual and potential transplant recipients.

1. DUE PROCESS AND EQUAL PROTECTION CONSIDERATIONS IN HEART TRANSPLANTATION

In the last two decades, a dramatic change has occurred in medical care. While in times past, major developments in medicine were primarily associated with advances in the control of infections and infectious diseases, technology has now come to dominate our perceptions of medical innovation. This change in emphasis has been accomplished by the unchecked diffusion of many new diagnostic and treatment modalities, without the simultaneous weighing of their costs and benefits. Many critics have thus called for a halt to indiscriminate increases in government health care expenditures, and for externally imposed changes in medicine's incentive structure and our attitude toward medical technology diffusion.

Because of its high visiblity and high cost, heart transplantation has become a focal point of such policy debates; as transplant techniques and heart transplantation becomes more widely available, vital policy issues will inevitably be raised--issues that will become even more critical as the procedure gains increasing public recognition as a possible (if not affordable or obtainable) treatment for a life threatening condition. One of the most pressing issues will be the extent to which the federal government should underwrite the costs associated with heart transplantation, and the corresponding fiscal implications such undertakings will have for the already overburdened Medicare system. While reimbursement issues have the greatest immediacy, the diffusion of innovative, but costly technological procedures such as heart transplantation raises additional concern. Chief among these are: (1) public exposure to

unsafe or inefficacious medical procedures or practices, (2) inefficient use of scarce medical resources, (3) escalating costs associated with hospital care in general, and (4) the equity concerns that may arise if certain medical treatments, developed with the assistance of public monies, can be made available only to a few because of physical or financial resource scarcity.

These concerns may lead the government to play an increasingly active and important role in controlling the diffusion of these technologies. Despite the current emphasis on market oriented rather than regulatory solutions, another impetus to governmentally sponsored reform may be provider and insurer reluctance to engage in cooperative activities aimed at reducing duplication of services because of fear of antitrust liability.

If the government does decide to act, its role could assume many forms. Medical procedures or professionals could be directly regulated by state or federal law, indirectly regulated via conditions imposed on receipt of federal financial assistance, or informally regulated by government coverage decisions.

The mechanism with the fewest aspects of formal regulation is coverage policy making for government financed health programs. Because its most immediate concern is with controlling the costs associated with such programs, the federal government may refuse to reimburse or may limit the amount of reimbursement for particular medical services and procedures that it finds to be insufficiently cost effective. While such coverage decisions may not be attempts to regulate the actual performance of such procedures, the monetary

incentives or disincentives that they create may have a powerful affect on the patient's ability or willingness to undergo expensive forms of treatment, and may also affect the ability of the transplant center to choose patients free of financial considerations. Thus, coverage policies may have a strong impact on decisions to open or close transplant facilities or to expand or constrict services, which in turn will affect the availability of non-reimbursed care.

Increasing concern over hospital cost containment, limited resources, safety, efficiency, and equity of access may lead the government beyond simple coverage limitations to more formal restrictions via conditioning the receipt of federal financial assistance, or direct state or federal statutory or administrative regulation. If the government chooses to act by conditioning the receipt of federal monies, the scope of the condition could be limited to activities affecting reimbursed care only, or broadened to apply to all transplant activity, whether reimbursed or not. Thus, the Health Care Finance Administration could choose to limit Medicare reimbursement for heart transplantation to centers or physicians who meet certain qualitativee standards. Alternatively, it could condition receipt of a variety of federal monies on imposition of qualitative standards on all transplant activity undertaken by the provider or facility. Through similar mechanisms, the government could require utilization of strict patient selection criteria, either for potential Medicare beneficiaries or for all transplant candidates. Rather than impose qualitative standards or patient selection criteria, the government could place an absolute limit on

the number of centers or surgeons who could be reimbursed for transplant services. Or more drastically, use the funding power to secure compliance with a permit system that would limit the number of centers or surgeons who could engage in transplant activity at all. Such mechanisms could also be used to establish regional transplant facilities.

The federal government could also seek to impose conditions on the states rather than on the individual health care providers. It could, for example, require the states to enact facility or health care professional licensures laws as a condition of receiving federal financial assistance. This form of regulation of state activity is exemplified by a federal statute that conditions state receipt of federal health care funds on state enactment of a certificate of need law.

The state or federal governments could also regulate directly through the enactment of statutes that would apply regardless of status as a recipient of financial assistance. Thus, they could seek to impose across the board certification or licensure requirements or limit transplant activities to designated regional transplant centers. At the farthest end of the regulatory spectrum, the government could seek to prohibit the performance of procedures such as heart transplantation altogether. While the probability of the adoption of this latter alternative is extremely remote, it has been legitimately discussed as a means of achieving equity of access to scarce medical procedures.

Thus, a wide range of policy options exist for reimbursement and regulation of high cost technologically oriented medical procedures such as heart transplantation. At one end of the spectrum, the federal government could seek to affect the diffusion of procedures such as heart transplantation through simple coverage decisions alone. At the other, it could seek to prohibit or restrict severely the use of such procedures by statute. But the federal government or the states could also choose any of a number of intermediate approaches. However, before any action along these lines can be taken, constitutional concerns about the legitimacy of the options will have to be addressed. For example, would government limitations or conditions on federal health care reimbursement unconstitutionally infringe on an individual's right by reducing his or her ability to effectuate a decision to undergo a particular form of treatment? Would all forms of government regulation of the availability or utilization of such a procedure be constitutionally permissible?

Given the likelihood that the public increasingly will demand access to heart transplantation and other life saving biotechnological innovations, these and other questions assume immediate importance. Even if the law is not fully developed on these points, it is likely that the public, medical professionals, and other members of the health care industry will press for legal clarification of these issues.

Throughout the recent history of health care in the United States, the major issues of political concern have been the improved quality of, and increased access to medical care. Government support

for health care grew at a rapid rate, and technological progress improved the quality of medical care in many areas. This progress in improving the quality and availability of health care services has led to a more recent concern over broader health policy issues, such as the overall cost of health care. A natural outgrowth of this focus has been widespread discussions of how such services might be better allocated or rationed--by both the government and private decisionmakers--in order to combat the problem of cost escalation. The major focus of these discussions has been the effective legal constraints on the process of rationing and/or allocating medical care, and the substantive criteria by which government and private decisionmakers undertake such allocation.

2. GOVERNMENT REGULATION OF HEART TRANSPLANTATION

If the right to choose to undergo a particular form of medical treatment, such as heart transplantation, is recognized as a protective aspect of the right of privacy, the courts then will have to examine the permissible limits of governmental regulation of such procedures. Under constitutional privacy standards, the validity of state involvement may depend on the form of governmental action--whether it involves direct regulation or reimbursement limitations--and the goals that the state seeks to establish through such regulations. As already noted, for example, the government may institute the policy of refusing to reimburse or limiting reimbursement for particular medical services and procedures that it finds to be insufficiently cost effective. It could also choose to limit reimbursement by allowing payment only for procedures performed

at particular facilities (or by particular surgeons). This type of limited reimbursement plan might be viewed as a means to facilitate efficient use of expensive and scarce equipment and personnel, reduce oversight and regulatory burdens, and perhaps even as a means of capping costs, because it would limit the number of reimbursed procedures to the number that the chosen facilities could actually accommodate. Policymakers may also favor such a system because they feel success ratios may be enhanced by limiting reimbursement to physicians or surgeons with proven records of success.

Because the right to choose to undergo particular forms of medical treatment has received only limited examination and recognition by the courts, much of our analysis is speculative. However, the following conclusions appear justified in light of current constitutional doctrine. First, no individual is entitled to reimbursement as a matter of right unless the government affirmatively grants it. This conclusion applies whether or not the right to decide to undergo particular forms of medical treatment is accorded status as a fundamental right. Second, if the right is denied fundamental status, virtually all regulation will be constitutionally valid, as it will be examined under the rational basis test. The government's ability to regulate via the spending power would be broad as well. Third, if the right is accorded status as an aspect of the constitutionally protected right of privacy, the courts will have to define the contours of the right, and the importance of the state interests that will be asserted in favor of regulation.

Our analysis suggests how the courts may view several justifications for regulation of heart transplantation under a fundamental rights analysis. Generally speaking, it is likely that the courts would allow some regulation of this procedure. And although it is difficult and perhaps impossible to assess at this point in time what form of regulation would be constitutionally permissible, it is clear what type of analysis, and some of the factors will be that the courts will most likely consider should the fundamental rights argument be raised in a challenge to various types of heart transplantation policies. Finally, perhaps the most far reaching implication of this analysis is that it may represent the courts' approach to the regulation of many other biotechnological health care procedures.

3. THE ANTITRUST IMPLICATIONS OF THE REGULATION OF HEART TRANSPLANTATION

Application of state and federal antitrust laws in the health care area is a relatively new phenomenon. While this scrutiny of the health professions is relatively new, it is apparent that antitrust law may limit the ability of health care providers to control and coordinate the delivery and financing of specialized medical technologies such as heart transplantation. Section 3 outlines and briefly analyzes possible antitrust implications of actions undertaken by heart transplant providers and insurers.

Federal antitrust laws embody a belief in the fundamental economic policy that competition is the best allocator of economic resources, the best determiner of prices, and the best promoter of technological and material progress. They are designed to encourage

competition on the basis of price, quality, and service. Practices that interfere with a potential or current market participant's ability to compete on the merits of the product or service offered are subject to antitrust challenge. Increased emphasis on competition rather than government regulation, in health services delivery and financing has caused all activities of health care providers--including delivery of specific services--to be assessed with an eye toward identifying possible anti-competitive practices.

Financing and delivery of highly technological treatments for catastrophic illnesses may raise antitrust concerns beyond those present in the health care delivery system. Providers increasingly are turning to cooperation and coordination of highly technological services in order to promote more effective use of resources, to preserve quality of care in complex areas of medical practice, and to facilitate uniform quality-cost tradeoff decisions on behalf of the health care consumer. While the goals may be laudable, such activities may have adverse legal consequences because traditional antitrust analysis rejects the premise that industry-wide groups can serve as unbiased arbiters of price, quantity, and/or quality.

Among the various aspects of the delivery and financing of heart transplantation that may have antitrust implications are such concerns as staffing procedures for cardiology departments. Hospital's exclusive arrangements with physician-specialists to staff their departments are closing doors to outside providers. While the scope and nature of such arrangements vary widely, one feature is central to them all--the physicians providing the service in question

have the right to provide all such service, and the physicians not party to the arrangements are foreclosed from providing any of that service to the contracting health care facility. Because delivery of transplant services may be limited to a few health care facilities at a time when professional interest in the procedure as an accepted method of treatment is increasing, the problem of exclusionary staffing arrangements may be particularly serious for cardiology departments that maintain a heart transplant program.

Another potential area of antitrust concern involves attempts by health care providers to coordinate delivery of services among health care facilities. Renewed efforts to control costs, reduce duplication of services, and coordinate delivery of transplant services may tempt health care providers to determine among themselves which facilities in any given area will deliver which clinical services, or to allocate territories or patients among transplant facilities.

Specialty certification is also a likely area of antitrust concern. Due to the highly technological nature of transplantation, implementation by medical communities of formal certification processes for transplant service personnel may be in the offing. However, specialty certification has been the subject of antitrust dialogue in the legal community because of its conflicting pro- and anti-competitive effects upon the health care market place.

In this section our aim is to identify the potential application of antitrust principles to actions on participants in the transplantation service and financing systems. Our purpose was not to

analyze the economic characteristics of transplant activities, nor to assess whether it is possible or necessary to design regulations that would produce results superior to those of unfettered market interactions. Our goal was to highlight potential conflicts rather than to voice opinions on the legality of any specific course of conduct. Our preliminary analysis indicates that there are several potential areas of conflict between the antitrust laws and current or foreseeable activity related to transplantation.

4. SPECIAL MALPRACTICE ISSUES IN HEART TRANSPLANTATION

In recent years, the frequency of organ transplantation has increased dramatically. Despite the surge in transplantation, transplant professionals have not experienced a corresponding increase in professional liability claims in stark contrast to health care professionals working in other areas of specialty practice. However, the evolution of transplantation procedures into standard medical practice may portend more uncertain times for transplant centers and providers. As patient expectations rise, and increasing numbers of centers and professionals engage in transplant practice, increasing numbers of liability claims can be expected. Existing legal principles will provide some--but not all--answers for many of these potential liability issues.

The organ donation and retrieval process presents a number of interesting, and only partially resolved, questions surrounding the responsibilities and potential liability of transplant centers and professionals. First, how far does the Uniform Anatomical Gift Act's grant of "good faith" immunity for transplant professionals extend?

Second, may a physician be held criminally or civilly liable for his or her determination that death has occurred and organ retrieval may proceed? Third, what effect do autopsy statutes have on organ retrieval efforts, and what is required of the transplant professional under these laws. Patient referral and care of transplant recipients may also raise unique and highly complex legal issues. First, may health care providers in the future be held liable if they fail to refer persons with heart conditions amenable to treatment by transplantation to transplant programs? Second, what role does--or should--informed consent play in transplant practice? Third, what types of malpractice actions involving transplant providers can be anticipated? And fourth, what liability exposure might the provider have for transplantation of defective or diseased organs into a recipient?

Court cases involving organ donation from living donors have generated a great deal of legal and ethical discussion. The courts have had to wrestle with the difficult problem of defining when, and under what conditions relatives may give legally valid consent from organ removal from mentally incompetent individuals or children in order to save the life of another family member. Another litigated issue has been whether a donor may recover damages for organ removal by claiming that the donation was necessitated by negligent treatment of the donee. These issues obviously do not come into play in cardiac transplantation, as the only source of organs is the cadaveric donor. However, cadaveric organ retrieval raises some unique legal issues of its own, questions that have garnered much less attention in both courts and the literature. Three important issues that may affect

providers involved in transplantable heart retrieval are: (1) the validity of consent for the use of the organs in compliance with the terms of the Uniform Anatomical Gift Act, (2) the timeliness of the determination of death, and (3) the removal of organs when death is by violent means and the medical examiner or coroner has jurisdiction over the body.

Transplantation practice involves legal ramifications not only because it involves interventions upon a donor, but because it may affect potential and actual transplant recipients as well. Medical malpractice and informed consent issues involving organ recipients will undoubtedly be raised as transplantation is increasingly utilized. Section 4, however, begins with a discussion of another, rather unique question. Can a health care provider be held liable for negligently failing to (1) advise a patient who may be a good transplant candidate of the existence of the transplantation as a viable form of therapy, and (2) refer that patient for such an evaluation?

The answer is "perhaps." As a general rule, physicians have a duty to advise their patients of alternative methods of treatment for their illnesses. Failure to explain a standard treatment alternative, if one exists, is generally held to be negligence. Courts have held that the duty to inform the patient of treatment alternatives exists even though the physician may not be competent to offer all of these forms of treatment him or herself. The physician thus retains a duty to acquaint the patient with general information

about treatment alternatives and to refer the patient to another health professional who performs that treatment.

In most typical cases involving the failure of the physician to inform, liability is grounded in the failure of the physician to keep up with advances in the medical profession. One likely reason that physicians may fail to recommend heart transplantation to their patients who are nearing the final stages of cardiac disease is that they are simply unaware of the advances in transplant practice. However, heart transplant cases differ from the usual situation in two important respects. First, despite increasing survival rates, heart transplantation is undoubtedly considered outside the realm of standard practice. Second, unlike many other forms of treatment, resource scarcity may play a role in determining liability for failure to inform. Because of the limited availability of donor organs, there is simply no guarantee that a person who is medically suitable for transplantation will be able to undergo treatment. These two factors may influence a court's decision on the question of whether a duty to inform exists at all. Failure to prove that treatment could have been obtained, even if the physician had advised the patient of it, will also be a factor in determining whether the failure to refer "caused" the injury to the patient. Because of the perception that the likelihood of acceptance is small, even the physician who accepts the therapeutic value of transplantation may not wish to advise a potential transplant candidate of the possibility of transplantation.

What should the transplant provider disclose to the recipient in order to obtain an informed consent? The two most critical

elements of informed consent to transplantation are insuring that the patient fully understands (1) the material risks and complications associated with transplantation, and (2) the likelihood that the transplant will succeed. Beyond current legal requirements, a truly informed consent to heart transplantation may also involve acquainting the patient with the often serious fiscal and psychological ramifications that transplantation can have for the patient and his or her family. In general, consent should involve a discussion of the diagnosis, the nature and purpose of treatment, feasible treatment alternatives, the prognosis if the proposed treatment is not given, material hazards and possible complications of treatment, including infection, graft rejection, the risk of transplant related cancer, miscellaneous complications of transplantation, and the probability of success.

CHAPTER 32

THE PATIENT AND ENTITLEMENT TO BENEFITS

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Section 1 - PATIENT SELECTION FOR HEART TRANSPLANTATION AND THE HANDICAPPED

A. INTRODUCTION

Since the enactment of Section 504[1] of the Rehabilitation Act of 1973[2] and the promulgation of its implementing regulations,[3] violations of the civil rights of the handicapped have been increasingly recognized and litigated. Despite its broad prohibition of discrimination in any program or activity receiving federal financial assistance, most litigation under the Act has focused on discrimination in access to public transportation and buildings, employment, and education. Until the recent public furor over the "Baby Doe," case [4] little attention was given to the potential impact of Section 504 on the activities of health care providers. The question of withholding treatment for handicapped newborns, however, is not the only area of medical practice that is affected by Section 504. Potential exists for charges of handicap discrimination in at least one other new and as yet unexplored area of health care--patient selection for medical treatments such as heart transplantations.

In the past two decades, scientific and medical research has developed remarkable new curative and restorative techniques. Heart transplantation and similar high technology medical procedures are being used with increasingly positive outcomes. However, procedures such as heart transplantation, which involve resource scarcity of one type or another, often impose a difficult duty on the health care provider--the necessity of choosing a few out of many in need for potentially lifesaving treatment. Each year as many as 75,000 people

have conditions that require heart transplantation.[5] However, it is estimated that only 1,000-2,000 donor hearts may be available each year.[6] Moreover, because procedures such as heart transplantation are not yet fully within the realm of accepted therapy, physicians may well chose patients on the basis of factors other than ability to benefit from treatment. They may, for example, select patients with no other physical or mental abnormalities in order to facilitate the assessment of the side effects of, or contraindications to, transplantation. In addition, the highly technological and quasi-experimental status of the procedure may also limit treatment availability, as only a few hospitals have active transplantation programs or are capable of undertaking them.

Resource scarcity, as well as the quasi-experimental nature of organ transplantation procedures, necessitates selection--and selection in the allocation of medical treatment presents some of the same thorny issues of handicap discrimination as those currently arising in the context of education and employment. Patient selection, no less than college admissions or hiring, may necessitate the selection of a few out of an applicant pool of many. As in education and employment decisionmaking, reliance on stereotypes or presumptions of unfitness in patient selection may often erect barriers for the handicapped person that do not exist for others. Similarly, facially neutral selection criteria may also unfairly exclude the handicapped.

Patient selection for medical treatment presents unique challenges for defining discrimination and for interpreting the Rehabilitation Act. Due to the novelty of the transplant procedure, and the

uncertainty of what the true contraindications to transplantation are, defining and detecting discrimination in patient selection poses problems. Is it a legitimate goal to select those candidates judged to have not merely a fair, but the greatest probability of surviving transplantation? To what extent should patient selection decisions be based on evaluations of emotional stability, a factor in survival, or upon criteria such as the presence of a stable home life or past psychological history, criteria that may exclude some of the handicapped? When may patients with a secondary physical or mental disability claim that they have been unfairly denied entry into a transplantation program?

This section explores the potential impact of Section 504 of the Rehabilitation Act of 1973 in the patient selection process for heart transplantation, a provocative testing ground for application of the law. Application of the law against handicap discrimination to decisionmaking in this area can make at least two important contributions to policy discussion. First, it can alert governmental agencies and health care providers to the duties and limitations that the Act may impose on patient selection arising out of resource scarcity or research preference. Second, an analysis of the Act in the medical services context can also help to illuminate the difficulties of defining handicap discrimination in a setting in which the treatment program is still in its formative stages.

This section will survey the current patient selection practices of heart transplantation programs throughout the country. It will then focus on the Rehabilitation Act and the extent to which current

methods for patient selection may be constrained by application of Section 504. The next section focuses on the crucial threshold questions concerning the applicability of Section 504 to heart transplantation practice: Is a heart transplantation program a "program or activity" under the Rehabilitation Act? Is it a "health benefit or service" within the meaning of the Section 504 regulations, or can it be excluded as an "experimental procedure"? The last section explores the applicability of the Rehabilitation Act's anti-discrimination provisions to the patient screening process and some of the difficulties with the Act as applied.

B. SCOPE OF THE PROBLEM: HEART TRANSPLANTATION

Heart disease is, and is likely to remain, a catastrophic disease of major proportions--killing or crippling vast numbers of individuals. The leading cause of death in the United States is coronary heart disease, accounting for two-thirds of all cardiovascular deaths.[7] In 1978, it alone was responsible for nearly 650,000 deaths. More than 150,000 of these occurred in people less than 65 years old. It is currently estimated that nearly one-third of the deaths from all causes in persons between the ages of 35 and 64 years are due to coronary heart disease, and nearly 40 percent of all deaths in white males aged 55 years and over are caused by the disease. For more than half a century cardiovascular diseases have led the list of the nation's killers.

Cardiovascular disease has extensive economic and social costs. For example, it accounts for more bed days than any other single

condition. The total economic cost of cardiovascular diseases is believed to be in excess of $60 billion annually.[8] At present, the only treatment for the end-stage cardiac disease (ESCD) patient facing imminent death is transplantation--the replacement of his or her damaged heart with a healthy heart from a person who has just died of other causes. At present, however, only a limited number of these individuals are viable candidates for cardiac transplantation because among persons with coronary heart disease, there is a critical limitation--sudden onset of death before the individual reaches the hospital. Patients suffering from other less-serious heart conditions will probably supply a comparatively smaller percentage of potential transplantation candidates, because they are likely to have other diseased organs that preclude transplantation, or have available to them alternate medical and surgical therapies that at the present time offer greater promise of success at a smaller risk. In addition to these problems, a major roadblock to widespread acceptance of transplantation as a therapeutic technique is the problem of rejection and its treatment through effective immunosuppression.[9] Problems associated with transplantation--infection, rejection, and malignancy --are all related to current methods of immunosuppression. Once the immunosuppression problem is solved, however, the demand for heart transplantation could rise dramatically.

For some time to come, only a small percentage of those who suffer from heart disease can be treated by having their damaged organ replaced by a healthy one. Yet the large number of persons with some form of cardiac disease still includes a substantial number who can

benefit from transplantation.[10] Because of the relatively large number of potential applicants and the great need for selectivity, potential clashes with anti-discrimination laws are likely.

C. CURRENT PRACTICES FOR PATIENT SELECTION

Although some aspects of heart transplantation are still in the experimental stages, a consistent pattern has emerged with respect to patient selection. In one transplantation program, potential heart transplant candidates are assessed for treatment suitability by a group that includes a cardiologist, a social worker, and a cardiac surgeon, all of whom have significant responsibility for direct patient care. Typically, the group accepts a number of patients roughly equal to the number of transplants that can be performed in any given period.[11] While they are not labelled as such, the program eligibility standards seem to be that: (1) the patient have a critical medical need for the transplant; (2) there be no alternate medical or surgical means that allow greater survival; and (3) the procedure have a reasonable chance of successful outcome given the current state of transplantation technology.

Specifically, in order to be considered for transplantation, a patient must have a New York Heart Association Class IV cardiac disability (essentially a bed-to-chair existence) and/or have an estimated life expectancy of less than six months.[12] In addition, the patient must have no medical contraindications to treatment, such as a recent history of pulmonary embolism, and other major organ systems also must be free from disease and infection.

Heart transplantation specialists have also singled out several psychosocial characteristics as bearing on the patient's survivability. According to current practice, the patient should have a strong "will to live," as well as the ability to endure the stress and tension caused by the pain of treatment and the need for a serious adjustment in lifestyle during the treatment and rehabilitation period.

Transplantation teams have translated these general psycho-social requirements into several specific patient selection criteria. To assure the proper mental attitude and to facilitate the patient rehabilitation process, the patient must have a stable or rewarding family or vocational environment to return to after the transplant. In addition, the patient may be excluded if he or she has experienced a history of alcoholism, job instability, or antisocial behavior.[13]

When patients are found to be otherwise suitable for transplantation, they are subjected to a variety of blood and histocompatibility tests.[14] Over the past decade, an array of systems for matching cardiac donors to recipients has been investigated. Only three systems have been demonstrated to be useful and/or practical. These include ABO blood type compatibility, negativity of the lymphocyte crossmatch, and compatibility for the human lymphocyte antigen HLA-A2. Mismatch on the A2 antigen appears to increase the probability that a long-term survivor will develop allograft coronary athrosclerosis . Matching on the basis of other HLA antigens, including those of the D locus, has not proven practical since the number of people awaiting a transplant is small, making it difficult to attain a close match between donor and recipient. Other

matching systems, dependent on cell cultures, although of potential value, have proven impractical because cadaver donors cannot be maintained for the time period long enough to complete the assay. With more medical centers instituting heart transplant programs, and with improved techniques of organ preservation, the recipient pools will become larger. With effective mechanisms for organ sharing, more precise histocompatibility testing may become realistic. In turn, better matching of recipients to donor hearts will markedly affect the process by which patients are selected, and no longer will ABO blood type and negative lymphocyte crossmatch be the major means of indicator histocompatibility. This section focuses on the first stage of the selection process--the initial determination of who is suited for treatment.

1. PATIENT SELECTION AND THE HANDICAPPED

Currently utilized selection criteria and mechanisms may be subject to attack under the federal handicap discrimination law because they may place barriers between treatment and the handicapped individual. Much like employee and college applicant screening, the discretionary nature of the patient screening process may be affected by the screener's unconscious biases against, or unfounded perceptions of, the handicapped. Discriminatory attitudes toward the handicapped, much like attitudes toward racial or ethnic minorities, remain embedded in our culture. Unlike race or alienage, however, a handicap --the trait that gives rise to the individual's legally protected status--may actually be perceived as a medical contraindication to treatment or as an indicator of emotional or mental instability even

though it may not affect that person's ability to benefit from treatment.[15] In addition, disabled persons are sometimes considered less able to make rewarding contributions to the community through social interaction.[16] This factor may be crucial in the allocation of scarce medical resources, because those considered most likely to make a positive contribution to society may be consciously or unconsciously favored for selection as transplant recipients.[17]

Use of ostensibly evenhanded selection criteria may also weigh against the handicapped in several ways. First, some disabilities--correctly or incorrectly--are adjudged to be medical contraindications to treatment. A severe diabetic, for instance, would probably not be considered as a candidate for heart transplantation.[18] Second, resource rationing and research considerations often dictate that the decision maker choose candidates who are least likely to suffer debilitating complications. Physicians in a new field may often be playing the medical odds--and may be disinclined to choose a person for treatment who has any history of medical or psychological debilitation. Third, some handicaps may limit or be perceived as limiting the individual's ability to adhere to a strict regimen during post-transplant rehabilitation. A heart transplantation recipient, for instance, must follow a rigorous post-operative treatment regimen consisting of drug therapy and altered life style (e.g., diet, exercise, etc). An applicant with a limited intellectual capacity may be excluded because of doubts about whether that individual could adequately maintain the necessary medication schedule. Fourth, the

use of exclusionary criteria may reflect stereotyped assumptions about the emotional or mental characteristics of the handicapped.

Thus, there are several points in the patient selection process at which the implications for potential exclusion of handicapped individuals should be carefully considered. The next section explores the potential impact that the Rehabilitation Act may have on selection practices for heart transplantation.

D. SECTION 504 OF THE REHABILITATION ACT OF 1973

Section 504 of the Rehabilitation Act of 1973 prohibits discrimination on the basis of handicap in any program or activity receiving federal financial assistance. It provides:[19]

> No otherwise qualified handicapped individual in the United States, as defined in Section 706(7) of this title, shall, solely by reason of his handicap, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving Federal financial assistance or under any program or activity conducted by any Executive agency or by the United States Postal Service.

While the statute itself amounts to a broad extension of civil rights protection to the handicapped, the bare language of the statute provides little guidance to its application in specific fact situations. To ameliorate this difficulty, the Secretary of Health, Education and Welfare issued regulations in 1979[20] to enforce the Congressional mandate of providing equal opportunity to the handicapped.[21] These regulations address some, but not all areas of controversy under Section 504. This section will discuss briefly several of the most pressing questions concerning Section 504's

applicability to patient selection for heart transplantation, drawing on both the regulations and case law dealing with Section 504 in other settings.

The questions that arise generally center on the scope and substance of the Act. First, what is the scope of the Rehabilitation Act? Is a heart transplantation program a "program or activity" under the statute? Must the heart transplantation program itself receive federal funds, or is it sufficient that the hospital receives them? Are experimental procedures within and thus subject to anti-discrimination laws? Second, what are the substantive issues? What does the term "qualified handicapped individual" mean in a transplantation setting? What limitations does the Act place on the use of selection criteria? What types of selection practices may violate the Act?

1. THE SCOPE OF SECTION 504

The initial inquiry in a Section 504 case is whether the alleged discrimination occurred in a program or activity that receives federal financial assistance. Included within the scope of the regulations are many programs to which the Department of Health and Human Services (HHS) provides assistance through many different kinds of recipients, including states, political subdivisions of states, and public and private agencies, institutions and organizations.[22]

a. The Meaning of "Federal Financial Assistance." In order to be subject to Section 504, health care providers must receive or benefit from federal financial assistance. The major controversy in this area has focused on the exclusion from coverage under Section 504

of "any federal assistance by way of insurance or guarantee contracts."[23] Providers of medical services have argued that Medicare and Medicaid are types of insurance and therefore do not constitute federal financial assistance. According to this argument, receipt of Medicare or Medicaid funds would not subject the actions of health care providers to federal scrutiny.

This issue was specifically addressed in the HHS regulations, where it was concluded that Medicare Part A[24] and Medicaid constituted federal financial assistance, but that Medicare Part B[25] did not. The merits of this approach have received little judicial attention,[26] but it remains the explicit policy of HHS.

Under the present interpretation, hospitals with transplantation programs will almost invariably meet the requirement of receipt of federal financial assistance, since nearly all hospitals receive Medicare Part A or Medicaid funds. Of course, receipt of other federal funds may also subject recipients to Section 504.

b. Who Must the Recipient Be? A second set of unsettled questions centers on whether the transplantation program itself must receive federal financial assistance in order to be subject to the Act. Health care providers have contended that the scope of Section 504 is limited to the specific program or activity receiving federal financial assistance and does not extend to the entire entity, or that general assistance to the hospital is insufficient to subject a particular program (that does not receive any separate federal financial assistance) to scrutiny under Section 504.

The applicable section of the HHS regulations suggests that a transplant program itself need not receive separate federal monies as long as it benefits from other sources of assistance to the hospital. It states that Section 504 applies to health programs that receive or benefit from federal financial assistance and to recipients that operate or that receive or benefit from federal financial assistance for the operation of such programs.[27] Whether or not the heart transplantation program itself is considered to be the "recipient," it appears sufficient that the hospitals receive some amount of assistance that benefits the heart transplantation program. As yet, however, the meaning of the term "benefit" has not been defined by the courts, and the directness and strength of the necessary benefit are unknown.

c. Section 504 and Experimental Procedures. Heart transplantation is still considered by some to be an experimental procedure,[28] while the regulations under Section 504 discuss only the provision of health benefits or services (in fact, most third-party insurers consider heart transplantations to be experimental). Thus, one could conceivably argue that transplantation programs are research endeavors rather than health services and are immune from the anti-discrimination provision of Section 504. However, this argument would in all likelihood be rejected, both because heart transplantation is in large measure a health benefit or service (even though it has experimental aspects) and because Section 504 extends beyond the programs listed in the HHS regulation to "any program or activity receiving federal financial assistance." This analysis is borne out by an examination of the Section 504 regulations issued by the

National Science Foundation (NSF),[29] an agency that disburses scientific research funds. The NSF regulations define and discuss "qualified handicapped individual" with respect to participation in scientific and technical experimentation.[30] Thus, even if cast as a research activity, heart transplantation would still fall within the scope of Section 504 if it received federal financial assistance.

These arguments may arise out of concern that Section 504 will interfere with the ability of physician-researchers to select patients on the basis of factors relevant to research objectives. However, the Act does not prohibit the use of selection criteria or practices necessary to the fulfillment of legitimate research objectives.[31]

Thus, while several of the questions addressed in this section have not been definitely settled, heart transplantation programs do appear to be subject to federal scrutiny under Section 504. The next section describes the effect of the substantive provisions of the statute on patient selection procedures and practices.

2. SUBSTANTIVE ISSUES

Section 504 prohibits discrimination against otherwise qualified handicapped individuals. Before discussing what it means to be a"qualified" individual in the heart transplantation setting, it is useful to briefly describe who is considered handicapped under the statute. As will be seen, the definition is very broad and may apply to a relatively large number of potential transplant recipients.

a. Who Are the Handicapped? The Rehabilitation Act provides a definition that has three criteria, any one of which may result in an individual being considered handicapped. A handicapped person is one who:[32]

- has a physical or mental impairment which substantially limits one or more major life activities; or
- has a record of such impairment; or
- is regarded as having such an impairment.

Neither the Act nor the regulations provide a list of the specific handicaps covered, but the regulations do supply broad definitions of disorders that will be considered impairments. Among these conditions are physiological disorders or conditions involving the neurological, musculoskeletal, cardiovascular, and respiratory systems, in addition to the special sense organs. Additionally, such mental or psychological disorders as mental retardation, organic brain syndrome, emotional or mental illness, and specific learning disabilities are included within the meaning of "impairment." Alcoholism and drug addiction are also impairments for the purposes of distribution of health benefits.[33] Moreover, if a cosmetic disfigurement or anatomical loss affects the specified body systems, such a condition is an impairment. The regulations also list additional systems and parts of the body that may be used as a basis for defining a handicap.[34]

Under the first part of the definition, it is not enough for an individual to have one of these conditions--the condition must

limit one or more of the individual's major life activities. These include functions such as walking, seeing, hearing, speaking, breathing, learning, and working.[35]

The second part of the definition includes persons who have a history of a handicapping condition but no longer have the condition, and persons who were once incorrectly identified as having a handicap. Examples of persons with a history of handicap are persons with a history of cancer, or mental illness. These persons may have recovered, but their past records still provide the basis for discrimination against them. Examples of persons who have been misclassified are those who have been classified as mentally retarded because of ethnic or cultural bias rather than on the basis of accurate criteria.[36]

The last part of the definition encompasses persons who may not have a handicap or a record of such handicap, but who nevertheless encounter discrimination that indicates that they are considered handicapped. Examples of this category are individuals with limps or disfiguring scars. Some confusion may arise in the transplant situation over what constitutes the relevant "handicap". Persons with end-stage cardiac disease (ESCD) are all handicapped under Section 504 because they have a cardiovascular infirmity that substantially limits one or more of their major life activities. However, discrimination among these individuals can occur if a transplantation program eliminates from consideration persons with additional handicapping conditions that do not limit their ability to benefit from treatment (or some other essential eligibility requirement). By way of example, a blind

ESCD victim may be impermissibly denied access to a transplantation program on the assumption that blindness limits his or her ability to benefit from treatment, even though every applicant is "handicapped" under the Act. Therefore, Section 504 can be applied in the patient selection setting to reduce discrimination among handicapped individuals based on a second handicapping condition.

b. Who is a Qualified Handicapped Individual? Section 504 does not bar discrimination against the handicapped unless they are "otherwise qualified" to participate in or benefit from a program. In Southeastern Community College v. Davis,[37] the Supreme Court held that the term "otherwise qualified" refers to a person who is qualified in spite of rather than apart from his or her handicap. An institution is therefore not required to disregard the disabilities of the applicant if his or her handicapping condition is relevant to reasonable program acceptance standards. The Court's ruling in Davis indicates that a handicapped person may be excluded from a federally funded health program if he or she doesn't meet the program's essential, physiologically- or mentally-based eligibility requirements.[38] Such physical or mental requirements must, however, be legitimate and necessary.[39] Thus, the Rehabilitation Act does not prohibit reasonable, necessary, physiologically- or mentally-based requirements of a transplantation program, even if they result in the exclusion of some handicapped individuals. These individuals are not "qualified" for heart transplantation and are thus not protected by the Act. The Act can, however, be used to scrutinize selection standards and program requirements to see if they are legitimate and fairly applied.

With these principles in mind, it is useful to examine heart transplantation patient selection practices in the context of Section 504. If patient selection practices were challenged under Section 504, the following questions are likely to arise. First, may physicians exclude handicapped individuals with a reasonably good chance of successful clinical outcome if their handicap or some condition associated with it makes them less qualified than other applicants? Second, what selection standards and criteria may be legitimately employed without violating Section 504? Third, what types of screening practices other than use of biased criteria may violate Section 504? These questions are addressed in turn below.

1) Picking the "best qualified" transplant recipients. To our knowledge, no court has addressed the issue of comparative medical evaluations in the allocation of scarce medical treatment under Section 504. However, an analogous problem has arisen in the context of medical school admissions, and the court in that case used broad language that is relevant to permissible patient selection practices. That language could be applied by analogy to sanction comparative medical evaluations that result in the exclusion of handicapped persons who meet all reasonable transplant program requirements, if other non-handicapped persons have a better prognosis.

The case, Doe v. New York University[40] involved Jane Doe, a woman with a long history of severe psychiatric disturbances, including several attempts at severe self-mutilation. Ms. Doe was admitted into NYU medical school after falsely misrepresenting in her application that she did not have any chronic or recurrent illnesses

or emotional problems. In 1976 during her second semester, she re-exhibited her previous self-destructive tendencies and was given a leave of absence with the understanding that she could apply for readmission. Shortly thereafter, she was diagnosed as a "borderline personality."[41] After undergoing treatment in California, she reapplied but was denied admission. She was, however, admitted into Harvard's School of Public Health where she earned a Master's degree. During the pendency of her Master's degree program at Harvard, she renewed her efforts to be re-admitted to NYU. After re-interviewing her and getting the opinion of a mutually agreed upon psychiatrist, NYU refused to re-admit her based on the psychiatrist's diagnosis. Ms. Doe then filed suit, claiming that the psychiatrist's report could not be validated as a predictor of success in medical school and that NYU had denied her readmission in violation of Section 504.[42]

Ms. Doe was required to exhaust her administrative remedies before the district court would hear her case.[43] However, when the court considered the case in 1981 it concluded that Ms. Doe was "otherwise qualified" since it was "more likely than not" that she could complete her studies and become a competent physician.[44] This finding was based in part upon the fact that she had not engaged in any self-destructive or anti-social behavior since 1977 and had been working in a stressful job where her performance had been evaluated as excellent. On the basis of its findings and its analysis of Section 504, the district court granted a preliminary injunction and ordered NYU to re-admit her in 1981.[45]

In reviewing the lower court's opinion, the court of appeals concluded that "n[o] deference was given to NYU's evaluation of Doe's qualifications as compared with those of other qualified first year students."[46] The court sanctioned the use of comparative psycho-social evaluations, stating that:[47]

> . . . the qualification of a handicapped person for admission into an institution turns not only on whether he or she meets its reasonable program requirements, but on whether the individual, where a few must be chosen out of many, is as well qualified despite the handicap as others accepted for the limited number of openings.

In effect, the court stated that where there are more qualified applicants than openings, the institution is not required to accept a handicapped individual who meets all reasonable program standards if the handicap renders that individual less well qualified than other applicants.

In light of the opinion's broad wording, there is little reason to believe that the holding is confined to the school admissions context. Rather, it implies that where a medical or psycho-social characteristic is relevant to successful program participation, the institution can take it into consideration when weighing the candidate's relative merits, and exclude those handicapped individuals who rank comparatively lower on this factor. The case is also significant because the same requirement of emotional ability to withstand stress is the basis for the imposition of psycho-social patient selection standards in both educational admissions and selection for heart transplantations.

Despite the likelihood that other courts may follow the lead of the Second Circuit Court of Appeals and hold that choosing those with maximum likelihood of successful clinical outcome will not violate the requirements of Section 504, patient selection ostensibly based on this goal may still violate the statute where the quality measured is relevant only up to a threshold level, and comparative evaluations are made beyond that point. Distinctions between the handicapped and non-handicapped may become irrelevant after this threshold level is met. For example, if one needs to have some degree of emotional stability to undergo heart transplantation, does it matter that another individual is more stable, if emotional health only impacts on survivability on the lower end of the scale? If it does not matter, then such a characteristic is no longer relevant to reasonable acceptance standards and exclusion on the basis of emotional stability may violate both the spirit of the regulations and the holding in Southeastern Community College v. Davis.

Past history in the area of medical practice indicates that reliance on irrelevant factors in patient selection is possible, if not likely. Consider, for instance, the case of insulin distribution to diabetics when the drug first appeared on the medical scene and was in extremely short supply. Patients were often excluded ostensibly because they did not possess sufficient strength of character to maintain the treatment regime. This exclusionary policy undoubtedly adversely affected individuals who would now be protected under the Rehabilitation Act. However, it is now widely believed that most persons whose lives depend on taking insulin and reducing their sugar

intake can do so. There is a strong possibility that the earlier view rested not so much on valid medical evaluation as on the pressure to invent some reasoned basis for the allocation decision, thereby avoiding the tremendous difficulties of rationally deciding who to leave to the ravages of a lethal condition when medical science offers the hope of a cure.[48]

Questions of handicap discrimination may also arise when the medical or psychological reasons advanced for denying admission rest on hard to prove or unproven assumptions. One court, interpreting Section 504 in a case involving psychological employment screening, has stated that conclusions based on nothing more than psychological theory are "weak and inadequate threads where...(someone's) entire future ... is at stake."[49] This reasoning can only apply more forcefully when it is life itself, rather than merely a career opportunity, that hangs in the balance.[50]

In summary, the only court case that addresses the issue of selecting the most qualified applicants suggests that Section 504 would allow selection of those with maximum likelihood of clinical success, even though this may result in the exclusion of qualified handicapped individuals. However, under the principles outlined by Davis and the regulations, such comparative exclusion cannot be continued after the factor loses significance as a predictor of outcome or survivability. Courts may also be more hesitant to exclude such individuals where denial rests on unsubstantiated medical or psychological theory.

c. Selection Standards and Criteria. Several principles may limit the types of criteria that transplant centers may utilize in selecting their patients. Under Section 504 and its implementing regulations, health care providers may not offer a handicapped individual who meets essential program eligibility requirements an opportunity to receive benefits that is not equal to that offered non-handicapped persons. Providers may not utilize patient selection criteria that have the effect of subjecting qualified handicapped individuals to discrimination on the basis of their handicapping conditions.[51] There have been no judicial interpretations of the applicability of Section 504 in the selection of patients for heart transplantation. Therefore, the analysis set out below is based on the analogy of Section 504's application in the education and employment settings.

Heart transplantation is an ordeal that is both arduous and risky. Transplant programs therefore seek individuals who are relatively healthy apart from their cardiac condition. In addition, they seek individuals with a strong will to live, and the ability to cope with the stress and tension caused by the pain of treatment and the need for adjustment in lifestyle. These goals have been translated into a number of discrete patient selection criteria. Discussion of these criteria will illustrate both the possibility for discrimination on the basis of handicap and the implications of Section 504 in the patient selection context.

From the literature, it appears that the relevant psychosocial patient selection criteria fall into a group of

contraindications and requirements. The major contraindications are: a history of alcoholism, presence of psychiatric illness, job instability, and antisocial behavior. The major requirement is a stable or rewarding family or vocational environment to return to following transplantation.[52]

These criteria and requirements, along with the more physiologically oriented criteria, can be divided into two groups. First are those that explicitly deny services to individuals on the basis of handicap. Exclusions based on "history of alcoholism" and "presence of psychiatric illness" fall into this category. Second are those that may disproportionately affect the handicapped although they appear neutral on their face. Both "job instability" and "presence of a stable family or vocational environment" can be placed in this category. These two types of criteria present different problems for defining the content of Section 504's anti-discrimination provisions. They therefore are analyzed separately below.

1) Handicap-specific exclusionary criteria. Some of the disability-specific selection criteria discussed above are considered to be either totally exclusionary or strongly adverse factors in the decision whether to admit the heart transplant candidate into the patient pool. For example, persons with irreversible and severe renal or hepatic dysfunction are either totally excluded or given very small hope of real consideration, as are persons with severe insulin-requiring diabetes. As mentioned above, some facilities may exclude or limit the participation of persons on the basis of histories of

psychiatric illness or alcoholism. All of the conditions mentioned above are considered handicaps under the Section 504 regulations.[53]

Following the approach taken in other selection contexts, handicapped individuals legally may be excluded from heart transplantation on the basis of their handicapping condition if all persons possessing such a handicap could not benefit from treatment.[54] A blanket exclusion of this type is not discriminatory because no individual with a condition that always disallows any reasonable chance of successful clinical outcome can ever meet the essential eligibility requirements of the program. Such individuals therefore would never be qualified under the Act.

However, persons sharing a particular type of handicapping condition often do not share the same level of debilitation. For instance, included among epileptics are the 50% who are seizure free with the prescribed medication, and the 30% who can control their seizures with the proper medication.[55] Similarly, the class of persons with a "history of mental illness" may include individuals who have experienced a nervous breakdown, persons diagnosed as acutely schizophrenic, and persons with intellectual disabilities of various types and degrees.[56] In short, the variation in types and levels of impairment among people with a specific handicap often dissallows meaningful generalizations about their chances for successful clinical outcome following a heart transplantation. Categoric exclusions of classes of handicapped individuals might be considered overbroad if used to exclude persons who can benefit from treatment.[57] Of course, the individual's handicapping condition may

nevertheless be relevant to the treatment decision. However, the admission decision would necessarily have to be based on an individualized consideration of that person's physical condition and prognosis.

Exclusionary criteria may be narrowed to focus on a small, uniformly affected group of handicapped persons. A refusal to admit because of a highly particularized handicap would be legitimate because of the inability of anyone in that class to meet the essential eligibility requirements of the program.[58]

Thus, criteria that excluded certain classes of handicapped individuals should pass muster under Section 504 as long as they are sufficiently narrowly tailored. A program might encounter difficulties if, for example, it excluded persons with all forms of diabetes unless none could meet the essential eligibility requirements of a heart transplantation program. By way of contrast, persons with insulin-requiring diabetes could probably legitimately be excluded as a class if they uniformly cannot meet the essential eligibility requirements.[59]

2) Facially Neutral Criteria. Section 504 prohibits both discriminatory actions that explicitly use handicap as criteria and actions that have the effect of discriminating on the basis of handicap.[60] Several of the recognized patient selection criteria that attempt to measure emotional stability may disproportionately effect the handicapped. For example, the presence of a stable family or work environment is often used as a measure of emotional stability. On its face, such a requirement does not exclude any group of the

handicapped. However, the handicapped individual often may be without the type of stable family or work background that the screeners seek.

The Office of Civil Rights of the Department of Health and Human Services uses a three part test to review health care policies or practices that may have a discriminatory effect on handicapped persons.[61] That test is outlined below, followed by a discussion of its application in the heart transplantation setting:

> First, does the policy or practice have a disproportionate, adverse effect on handicapped persons? If the policy or practice does not have a disproportionate adverse effect, it does not violate Section 504. If the policy or practice does have a disproportionate adverse effect, the second part of the test must be applied: Is the policy or practice related to a legitimate objective unrelated to handicap? If the policy or practice has a disproportionate adverse effect and does not further a legitimate objective, it violates Section 504. If the policy or practice has a disproportionate adverse effect and furthers a legitimate objective, the third part of the test must be applied: Are there alternatives that would further the same objectives but that would have a lower disproportionate effect? If such alternatives are available, the policy or practice violates Section 504.[62]

Several selection criteria, while facially neutral, may pose a risk of both disproportionately excluding the handicapped and violating Section 504. By way of example, some heart transplant programs may evaluate present and future emotional stability by reference to the candidate's ability to hold a job and by the stability of his or her family and work environment.[63] While these indicia may accurately reflect emotional stability for some non-disabled persons, for the handicapped such factors may not be appropriate. Handicapped individuals who are mentally and emotionally able to handle the stresses of heart transplantation are often unable to keep

or even obtain employment because of discriminatory attitudes among employers and fellow workers as well as unwillingness to accommodate the handicapped worker.[64] Similarly, the handicapping condition and the response of others to persons with such a condition may make it more difficult for the handicapped individual to attain the type of traditional stable family relationship sought by transplantation teams. The use of such selection criteria may therefore disproportionately exclude handicapped individuals from transplantation programs. Upon proof of such a disproportionate impact, the first prong of the test is satisfied.

The second prong of the test asks whether the standard or criteria is related to a legitimate objective unrelated to handicap. These criteria are all related to emotional stability, which in turn is presumed to impact upon survivability. Accepting for the moment that such objectives--choosing emotionally stable persons in order to assure survivability--is valid,[65] then the criteria must be measured against the third prong: whether there are alternative standards that would further the same objectives with a lower disproportionate impact upon any class of handicapped individuals. In the heart transplantation context, that alternative may simply be to individually assess each candidate on the basis of that person's current emotional stability by considering the opinion of the individual's physician, mental health professional or social worker if available and through personal interviewing.[66]

In sum, the following guidance can be offered to health care providers who seek to establish patient selection criteria that will

pass muster under the Rehabilitation Act: first, any criteria that specifically exclude or limit the opportunities of handicapped individuals must be narrowly tailored to reach only those individuals whose disabilities would uniformly impact upon ability to meet the essential eligibility requirements; and second, facially neutral criteria may not be used if they have the effect of discriminating on he basis of handicap.

3) Nondiscriminatory Application of the Criteria. Another type of discrimination may surface in admissions decisions even though the program standards and criteria are legitimate. Section 504 is also violated when the handicapped individual is rejected when he or she is assessed on the basis of unfounded conclusions about his or her handicap rather than on his or her individual qualifications.[67]

Such a situation arose in Pushkin v. University of Colorado,[68] which involved a wheelchair-confined physician with multiple sclerosis (MS) who was denied admission to University of Colorado's Psychiatric Residency Program. The interviewers, who were all psychiatrists, felt that MS victims were emotionally unstable due to both the nature of their illness and the necessity to take medication that tends to produce emotional fluctuations. They refused to admit Dr. Pushkin because they felt that his purported emotional instability would negatively affect his ability to handle psychiatric patients.

The memorandum opinion of the trial court included extensive findings of fact that supported its conclusion that Dr. Pushkin was

rejected because of his affliction. The trial court then assessed the legitimacy and factual correctness of the reasons articulated by the University for finding that Pushkin's handicap disabled him from meeting the program requirements. As the Tenth Circuit Court of Appeals noted:[69]

> The record is replete with testimony dealing with the inability of Dr. Pushkin to serve in the residency program based upon his handicap. These observations of the members of the panel are not predicated on any known deficiency of Dr. Pushkin himself, but rather these are reasons that are based upon the examiner's general knowledge of multiple sclerosis and their concern for psychologic reactions of the patient and in turn the doctor, as a result of his being in a wheelchair. The trial court concluded that these general reasons did not apply with regard to Dr. Pushkin, but that Dr. Pushkin was an otherwise qualified handicapped individual who was wrongfully, by sole reason of his handicap, excluded from participation in or denied the benefits of or subjected to discrimination under a program or activity receiving federal financial assistance.

This decision is especially significant for assessing the impact of Section 504 on patient selection practices as it involves a similar practice of evaluating candidates for emotional stability by professionals well versed in their fields. The court's recognition that even psychiatrists can fail to apply their established standards,[70] and its willingness to correct the failure through judicial intervention is significant, for the same failure could easily arise in the patient selection process. As the trial court in Pushkin noted, "such a failure is not uncommon where only subjective criteria are used to select a few from an applicant pool of many."[71]

The court went on to describe what it considered to be the essence of the University's error under Section 504:[72]

> I will not venture even a guess of whether Dr. Pushkin is or should be among the best qualified, but I hold that he did not receive the same consideration and that he was indeed treated differently because of his handicap.

Since the University could not establish that Dr. Pushkin was rejected for legitimate reasons, the Court ordered it to admit him into the psychiatric residency program.[73] A similar failure to apply established heart transplantation program standards in an evenhanded manner may therefore be deemed a violation of Section 504.

E. CONCLUSION

Because the regulations interpreting Section 504 are still relatively new, it is difficult to arrive at anything more than a tentative outline of the responsibilities and rights the Rehabilitation Act imposes. This is particularly true when this relatively untested law is applied in an unanticipated setting, one at the very periphery of medical science.

Although it arrives unanticipated, we must still face up to the possibilities of discrimination in health care allocation. We live in an era in which medicine holds the promise of effective treatments for many types of catastrophic diseases, treatments that are and will remain scarce due to fiscal and resource shortages. As the cost and complexity of medical care advance, physicians will increasingly be faced with the necessity to allocate scarce medical resources. Whether through assessment of treatment suitability, by lottery, or by chance, these allocations must stay within the confines of the applicable anti-discrimination laws.

Section 2 - TITLE VI AND HEART TRANSPLANTATION: DISCRIMINATION IN PATIENT SELECTION

A. INTRODUCTION

Title VI of the Civil Rights Act of 1964[1] prohibits discrimination on the basis of race, color, or national origin in federally assisted programs. Section 601 of the Act provides that:

> No person in the United States shall, on the ground of race, color, or national origin, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity receiving federal financial assistance.

While Title VI was enacted primarily to prohibit segregation in publicly funded schools, it applies equally to all recipients of federal funds, including institutions that provide health care. Because virtually all hospitals with transplant programs accept some form of federal financial assistance,[2] Title VI has implications for patient selection practices for heart transplantation. The potential impact of Title VI on patient selection for heart transplantation is difficult to assess because, to date, the Title VI enforcement program has not brought substantive issues of discrimination to the fore in even the most common areas of health care.[3] However, due to increasing concern over rising costs and the use of sophisticated technology, government scrutiny of all facets of health care and health care spending is likely to increase.[4] It is in this context that the issue of discrimination in the selection of patients for transplantation must be considered, because the regulatory and allocative decisions that are currently being made with respect to

heart transplantation may adversely affect racial and ethnic minorities.

The nature and extent of the problem of racially based inequities in heart transplantation programs are difficult to define precisely or to specify. However, substantial disparities may exist in the receipt of heart transplantation by race and ethnicity. In other areas of health care, evidence indicates that racial and ethnic minorities do not have equal access to medical services.[5] It is likely, particularly in light of the emphasis on selectivity in the heart transplantation setting, that this problem is or will be exacerbated in the heart transplantation patient selection process.[6]

The important question is whether any part of the disparity arises out of discrimination in the legal sense of the term and, if so, whether and when such discrimination can be legally attributable to the patient selection procedures of the government or specific health care facilities. While aspects of patient selection may raise Title VI issues, many cannot be definitively settled because of the difficulty in determining both the content and the scope of Title VI as it applies in this specialized area of health care.

The content issues concern the effect of Title VI on patient selection practices. They include choice of patient selection criteria, application of those criteria to the heart transplant candidate, and the impact of a range of environmental and socio-cultural factors on the representation of racial and ethnic minorities in the transplant recipient population. The scope issues involve the persons and institutions to whom the statute applies.

Even a cursory examination of the complicated arrangements through which patients are referred to heart transplantation programs and chosen for treatment suggests a number of difficult issues that can only be briefly discussed here: Who is responsible if a private physician makes discriminatory referrals to a transplant program? May a federal agency write and enforce regulations that would violate Title VI if written and imposed at the transplant program level? Is the transplant facility open to charges of discrimination if it utilizes discriminatory patient selection criteria that were promulgated by a federal agency?

The potential merit of many claims of discrimination in patient selection and referral rests on resolution of these scope and content issues. Yet these issues cannot be definitively addressed because they in turn reflect further uncertainties in two central areas of Title VI law. They are: (1) whether a discriminatory effects or intent standard is appropriate for Title VI litigation and enforcement, and (2) the meanings of "federal financial assistance" and "recipient" as they arise under Title VI.

The applicable standard substantially impacts on the content issues, because differential utilization of heart transplantation programs by racial and ethnic groups may arise out of facially neutral practices[7] actionable, if at all, only under the effects test. The second uncertainty--the meanings of federal financial "assistance" and "recipient"--is important to the scope issues because only health care providers who receive federal financial assistance, and are thus "recipients," are subject to Title VI.

Because the heart transplantation issues arising under Title VI are conceptually organized around these central areas of Title VI law, the remaining body of this section is structured to reflect this natural grouping into content and scope issues. Thus, we first address what patient selection practices may be affected by Title VI, and then take up who may be subject to the requirements of Title VI.

B. THE CONTENT ISSUES: DISCRIMINATORY INTENT OR EFFECTS?

Federal courts have not yet established a uniform standard by which to identify actions or practices forbidden by Title VI. While the U.S. Supreme Court has not yet spoken on the subject,[8] lower federal courts have divided on which test is the appropriate one under Title VI.

The effects test requires the plaintiff to present evidence of a disproportionate and injurious impact of the defendant's facially neutral action on the members of a racial minority group as a class.[9] Upon an initial showing of discrimination by the plaintiff, the burden shifts to the defendant to establish a legitimate justification for its action and to show that a less discriminatory course of action is not available.[10] By comparison, the intent test requires the plaintiff to present evidence of the defendant's discriminatory intent in addition to showing the disproportionate impact of the defendant's action. Under this test, the plaintiff must present evidence--direct or circumstantial--establishing that the defendant acted with a specific discriminatory purpose. Thus, evidence of impact, by itself, is insufficient to establish an illegitimate purpose.[11]

The choice between these threshold tests has become increasingly important as the nature of Title VI cases has changed. It is increasingly rare to encounter the kind of direct and overt discriminatory practices that originally prompted Congress to enact the anti-discrimination laws. While openly discriminatory hospital admissions policies and regulations were documented in the 1960s,[12] it would be extremely unusual today for any minority group to be refused medical services explicitly on the basis of race. Recently, Title VI claims have tended to focus on stereotypical or facially neutral practices rather than overt racial bias.[13] In these types of cases, the legal test of discrimination chosen by a court significantly affects the outcome of a case because the plaintiff often may be able to prove discriminatory effect but not discriminatory intent.

1. THE EFFECTS TEST

The standard used is important for our purposes, because patient selection practices and selection criteria will be challenged more easily under the effects test. For this reason, and because it is the test currently used by the federal office primarily responsible for enforcing Title VI in the health care area,[14] the U.S. Department of Health and Human Services' (HHS) Office for Civil Rights (OCR), we will concentrate on exploring the ramifications of the effects test for patient selection.

The regulatory basis for the effects test under Title VI is found in 45 CFR §§80.3(b)(2). It provides that:

> A recipient, in determining the types of services, financial aid, or other benefits, or facilities which

> will be provided under any such program, or the class of individuals to whom, or the situations in which, such services, financial aid, other benefits, or facilities will be provided under any such program, may not, directly or through contractual or other arrangements, utilize criteria or methods of administration which have the effect of defeating or substantially impairing the objectives of the program as respects individuals of a particular race, color or national origin [emphasis added).

However, neither this nor other explanations of Title VI's substantive provisions are specific enough to guide OCR staff and the courts, as well as recipients and beneficiaries, in determining compliance.[15] Civil rights enforcement actions have therefore frequently relied on interpretive rules that interpret those general obligations in specific factual contexts.[16] One of the most important areas in which the OCR developed policy was in specifying how the effects test was to be applied. As noted in the previous section, OCR evolved a three-part test for determining when a Title VI violation has occurred.[17] Although the test itself is rather simplistic, it does offer some guidance in determining when facially neutral policies or practices will violate Title VI.

The first part of the test asks whether the proposed criteria or action will have a disproportionate adverse effect on persons of a particular race, color, or national origin. If the action does not have such a disproportionate effect, it does not violate Title VI. If the action will have such a disproportionate adverse effect, the second part of the test asks whether the action is necessary to further legitimate governmental objectives unrelated to race, color, or national origin. If the action is not necessary to further such

legitimate objectives, it will violate Title VI. Even if the action furthers legitimate objectives, if alternatives exist that would further those objectives with a lesser disproportionate adverse effect, Title VI is violated under the third part of the test.[18] After briefly describing some current patient selection practices, we will discuss how the effects test may be applied in the patient selection setting.

a. The Test Applied to Patient Selection. Several of the recognized patient selection criteria currently used in heart transplant programs may disproportionately affect racial and ethnic minorities under the first part of the effects test. Our intent here is not to analyze exhaustively every patient selection criterion or practice that could be challenged under Title VI; rather, it is to indicate how OCR's effects test can be applied to patient selection practices for heart transplantation. To do this, we will focus on two patient selection criteria that may disproportionately effect racial or minority groups and indicate how they may be analyzed under the effects test. The reader should be cautioned that in so doing we are forced to paint with a very broad brush. With that caution in mind, the remaining portion of this section concentrates on two specific selection criteria for heart transplantation; one medical, one psycho-social. The first is exclusion because of severe renal dysfunction; the second is exclusion based on lack of a stable family environment to return to after transplantation.

As noted above, the first part of the effects test asks whether facially neutral criteria or practices disproportionately

effect a racial or ethnic minority. If the presence of severe renal dysfunction is used as a basis for exclusion from heart transplantation, this first part of the effects test will be met, because such a criterion will tend to disproportionately screen out racial and ethnic minorities, particularly blacks. While blacks constituted slightly more than 11.3% of the population as measured by the 1970 census, as of March 1977 the End-Stage Renal Disease (ESRD) Medical Information System indicated that blacks constituted 24.1% of the ESRD population.[23] Clearly blacks would likely be disproportionately excluded from heart transplantation by a criterion focused on renal dysfunction.

Similarly, an exclusionary criterion based on lack of familial support mechanisms could disproportionately effect blacks and other minority groups, especially if the criterion focused on factors such as the presence of the spouse in the household. The 1980 census figures indicate that married minority group members, particularly blacks, are disproportionately likely to have their spouse absent from the household.[24] Thus, any criterion that focuses on the presence of the spouse in the home may also disproportionately effect racial or ethnic minority groups.

However, a disproportionate effect on racial or ethnic groups, in and of itself, does not establish a Title VI violation. The second part of OCR's effects test proceeds to ask whether the action or criterion is necessary to further a legitimate government objective. Under a system of Medicare reimbursement for heart transplantation, strict patient selection criteria would relate to at

least the following two objectives: (1) assuring that those most likely to benefit from treatment undergo the procedure, and (2) controlling costs by keeping the number of potential recipients low.

While the question has not arisen in Title VI case law, selecting those transplant candidates most likely to benefit from the procedure is probably a legitimate objective.[25] Moreover, OCR has specified that realizing necessary fiscal savings is a legitimate objective unrelated to race or natural origin.[26]

If renal dysfunction limits the ability of individuals to benefit from heart transplantation, exclusion of individuals with that condition would further a legitimate objective and thus the criterion would pass the second part of the effects test. Similarly, the exclusion of persons without recognized familial support systems would probably pass muster under the second part of the test, since it would serve the same legitimate objective of aiding in the selection of those most likely to benefit from treatment, because interpersonal support systems have been shown to be important to successful rehabilitation from serious illnesses.[27]

The crucial issues surrounding any criteria used to select those eligible to receive heart transplants will probably focus on the third element of the test: whether alternative methods or criteria exist that will further the same objective with a lesser disproportionate effect. Exclusion because of severe renal dysfunction probably is not discriminatory under Title VI. If renal dysfunction is a true contraindication to heart transplantation, then no alternative method or criterion could be devised that could have a

lesser disproportionate effect on blacks while still meeting the legitimate programmatic objective of excluding those unlikely to benefit from treatment. Absent unforeseen factors, then, the exclusion would survive a Title VI challenge.

However, an exclusion focused on particular types of family support systems is more troublesome. Members of racial and ethnic groups may disproportionately vary from the predominant middle-American norms of living patterns, but the alternatives adopted may be just as likely to provide the strong interpersonal support necessary for successful recovery following the transplant procedure. Thus, there may well be alternative criteria or methods of selecting patients that would have a lesser disproportionate effect on racial or ethnic groups. For instance, an alternative policy of individually assessing the degree and extent of all forms of interpersonal support mechanisms could be used. Since an alternative method exists to further the presumably legitimate objective of choosing those who will rehabilitate quickly and successfully, the practice of excluding persons who vary from the traditional nuclear family norm may violate Title VI.

b. Treating Ethnic and Racial Groups Differently. Another type of discrimination may surface in admissions decisions even if the transplant program standards and criteria for patient selection do not violate Title VI. The screeners'[28] conscious and unconscious perceptions of members of racial and ethnic groups may influence their assessment of minority transplant candidates. If discriminatory intent need not be proven, Title VI is also violated when the

applicant, on the grounds of race, is rejected or treated differently from others in determining whether he or she meets any of the selection criteria.[29] While no systematic data in the heart transplantation setting are available, studies have noted racial/ethnic sorting processes in mental health care settings.[30] In light of the greater emphasis on selectivity in the heart transplantation setting than in most health care settings, the same kind of practices probably exist to a more significant degree in patient selection for heart transplantation. While such practices have never received formal legal attention, they may not conform to the mandates of Title VI.

C. THE SCOPE ISSUES

The analysis above concentrated on what types of actions may violate Title VI. The remaining analysis examines who, in the chain of persons who refer and select heart transplant candidates, is subject to the substantive provisions of Title VI.

Absent complicating factors, if the transplant facility utilizes discriminatory methods or criteria in patient selection, it may be held in violation of Title VI under the effects test. Yet other factors may account for low minority representation in the transplant recipient population.[31] For example, discrimination may have occurred further back in the chain of patient referrals to a transplant program. Who may be held in violation of Title VI if the referring physician discriminates and refuses, for example, to refer black individuals to a transplantation program on the basis of race? Is this a violation of the transplantation facility's Title VI

obligations? Can the individual physician be found in violation of Title VI? Second, is the Health Care Finance Administration (HCFA) subject to Title VI when it makes reimbursement decisions for the Medicare program? Could it impose patient selection criteria that would ordinarily violate Title VI on transplant facilities as a condition of their participation in a Medicare heart transplant reimbursement system?

The analysis in this section will first briefly consider whether racially imbalanced patient referral patterns violate Title VI. We then look at who may be legally responsible for that behavior. Finally, we consider whether federal agencies are subject to Title VI and the consequent ramifications for heart transplant patient selection policies.

1. DISCRIMINATORY REFERRAL PATTERNS AND PATIENT SELECTION

Are decisions regarding when, where, and if patients will be referred to a transplant program subject to Title VI scrutiny? To take the most blatant case, is a racially-motivated refusal to refer minority patients to a heart transplant program a violation of Title VI?

As noted earlier, the content of the term "discrimination," as it is used in Title VI, is hazy at best. However, both the regulations[32] and OCR's hospital guidelines[33] make some generalized comments that suggest that racially imbalanced referrals on the part of hospitals and physicians may both violate Title VI and obligate the transplant facility to discern the reason for the imbalance.

The HHS regulations state that recipients of federal financial assistance may not, on the grounds of race, color, or national origin:[34]

> Treat an individual differently in determining whether he satisfies any admission, enrollment, quota, eligibility, membership or other requirement or condition which individuals must meet in order to be provided any service, financial aid or benefit under such program.

The regulations define the term "program" broadly to include "any activity for the provision of services undertaken by the recipient [of federal financial assistance]."[35] While the term is undefined, patient referral would seem to be a "service" within the meaning of the regulations. Hence, refusal to refer suitable minority transplant candidates on the basis of race probably violates Title VI since it amounts to treating an individual differently in determining whether conditions for the provision of a service are met.

OCR's Hospital Guidelines[36] also suggest that patient referral practices may be subject to Title VI scrutiny. They provide that hospital referrals, "including but not limited to referrals to physicians, extended care facilities, and other post-hospital care programs, [must be . . .] made in a manner which does not result in discrimination."[37] Thus, referral practices as well as formal transplant candidate selection practices can be scrutinized under Title VI.

a. Responsibility for Discriminatory Referral. Title VI and its regulations discuss discrimination by recipients of federal financial assistance; transplant facilities, as recipients, are, of

course, responsible for their own discriminatory acts. The questions under analysis here are: (1) whether a referring physician could be subject to Title VI; (2) if the physician is associated with a hospital through either staff membership or hospital privileges, whether that hospital is responsible for the discriminatory behavior of the physician and therefore subject to action under Title VI; and (3) whether transplanting facilities have any duty to investigate and act on low minority utilization patterns. These questions are addressed in turn below.

To our knowledge, no suit against a private physician for discriminatory patient referral practices has ever been maintained in federal court. Despite the lack of legal precedent, individual physicians may be subject to the provisions of Title VI if they receive reimbursement under the Medicaid, and possibly the Medicare, programs.

Title VI and its regulations make no distinctions based on either the relative size or status (e.g., individual or hospital) of the recipient of federal aid, or on the amount of the federal financial assistance received. Indeed, the regulations define "recipient" to include "any individual . . . to whom federal financial assistance is extended . . . [but not including] the ultimate beneficiary of the program."[38] The major question then, seems not to be whether individual physicians can be subject to Title VI, but rather whether engaging in the treatment of Medicaid or Medicare patients will make them so. A secondary issue is whether the amount of reimbursement that the physician receives under the Medicare or Medicaid programs is relevant to the question of whether the individual physician must comply with Title VI.

As stated, individual providers will be subject to Title VI only if they receive "federal financial assistance." The major controversy in this area has focused on the statutory exclusion from the term "federal financial assistance" of any assistance by way of insurance or guaranty contracts.[39] Providers of medical services have argued that Medicare and Medicaid are types of insurance and therefore do not constitute federal financial assistance. According to this argument, receipt of any amount of Medicaid and Medicare funds would not subject the provider to scrutiny under Title VI. This is important to our discussion, since private physicians receive federal funds primarily through the Medicaid and Medicare Part B programs.[40]

This issue has been specifically addressed by HHS, which concluded that Medicare Part A and Medicaid constitute federal financial assistance but that Medicare Part B does not.[41] This position appears to center on the belief that Medicare Part B is a contract of insurance[42] and that Title VI does not apply to programs where payment is made directly to the ultimate beneficiary.[43] Under this view (the one under which HHS currently enforces Title VI), an individual physician who treats Medicare but not Medicaid patients would not be subject to Title VI and thus his or her discriminatory referral practices would not be actionable under Title VI.

However, the U.S. Commission on Civil Rights has twice analyzed the OCR's exclusion of Part B providers and has questioned its accuracy.[44] Its position is that physician participation in Medicare Part B as well as Medicare Part A of Medicaid programs is sufficient to make Title VI applicable. If this view is accepted, the

discriminatory referral practices of many more physicians may legally be called into question under Title VI. The merits of these competing approaches have received scant judicial attention,[45] but the Part B exclusion remains the policy of HHS.

Case law provides little information on the question of whether the substantiality of physician involvement in Medicare and Medicaid programs affects the applicability of Title VI to the activities of that individual. The regulations make no distinctions based on the amount of federal financial assistance received; however, the courts as well as OCR may be reluctant to pursue Title VI cases involving physicians with only a limited involvement in federal assistance programs. In the area of post-secondary education, one court has implied that the magnitude of the amount of assistance and the receipt of federal monies by the specific program in question are factors in determining the applicability of Title VI.[46]

In light of the limited resources available for enforcement, the OCR has done little to assure or even study compliance by individual providers. OCR relies on state Medicaid agencies and private parties to enforce physician compliance with Title VI, neither of which has resulted in any significant action.[47] This factor, plus OCR's limited array of penalties for noncompliance,[48] limits the potential effectiveness of Title VI in correcting discriminatory practices by physicians who refer their patients to heart transplant programs.

As stated, Title VI focuses on discrimination by the "recipient" of federal financial assistance. The issues here are

whether and when the discriminatory actions of the staff and associated physicians legally can be attributed to the hospitals in which they practice or to which they refer transplant candidates.

These questions, like most others in the area of discrimination in health care, have received virtually no attention. However, since salaried physicians are subject to the hospital's control, under the doctrine of respondeat superior[49] the hospital may have both a right and a duty to eliminate the racially discriminatory practices of the employees it hires. The OCR Hospital Guidelines indicate that hospital compliance with Title VI includes a duty on the part of the hospital to ensure that its staff physicians do not consider race, color, or national origin as a factor in selecting hospitals for their patients. They also state that hospital referrals must not be made in a manner that results in discrimination.[50] While the guidelines speak of refusal to refer patients to particular hospitals, they do not state that hospitals may be held responsible for the actions of staff physicians who do not refer minority patients to specific programs such as a heart transplant program. However, the passages cited above and the general flavor of the guidelines would seem to suggest that OCR would impose responsibility on the hospital for the refusal of its staff physicians to refer minorities to heart transplantation programs.

While the referring hospital may be liable for the behavior of its staff physicians, what responsibilities, if any, does the transplant facility have when low minority utilization is caused by lack of minority referrals from outside physicians? The control that

a hospital can exercise over non-employed physicians is a complex legal question that has not been addressed with regard to racial discrimination; the analysis offered here can only suggest broad outlines and implications.

Obviously, if a transplant facility wishes to avoid Title VI liability while maintaining racially discriminatory policies, it cannot do so by specifically instructing its referral physicians to screen out persons of particular racial or ethnic backgrounds.[51] However, if discriminatory effect rather than intent is the yardstick by which violations of Title VI are measured, then the question of hospital liability for underutilization caused by the behavior of referring physicians assumes broader significance. The outcome of any challenge to underutilization will likely depend on both the formality and continuity of the physician's affiliation with the transplant facility, as well as OCR's and the courts' willingness to give an expansive interpretation to the responsibilities of hospitals as recipients of federal financial assistance.

Under Title VI the transplant facility may have some indirect responsibilities as well. Hospitals have a duty under the OCR guidelines to determine the reasons for significant variations between the racial composition of the patient census and the available population census data for the service area and to take whatever action may be necessary to correct any discrimination.[52] While this obligation was designed to apply to overall hospital utilization rates for a geographically-confined patient selection area, conceivably its principle could be extended to require transplant facilities to

investigate and take action to correct low minority representation in its transplant selection pools. The nature and extent of this duty has received little attention from HHS, and it is unclear what actions could be required.

b. Nondiscriminatory Regulations for Patient Selection. As discussed above, transplant facilities, referring hospitals, and arguably some referring physicians who receive federal financial assistance must stay within the bounds of Title VI when making decisions pertaining to patient selection. However, HCFA, as the Medicare reimbursement dispenser and regulator, may also undertake actions that will affect significantly the selection of individuals who may be considered for heart transplantation. HCFA's responsibility to conform to Title VI when writing strict patient selection criteria depends in part on the extent to which the mandates of Title VI apply to a federal agency.

Title VI on its face applies only to programs and activities receiving federal financial assistance, and not to federal agencies dispensing federal funds or administering those assistance programs. While no court has ever so ruled in a Title VI case, one court has held that Section 504 of the Rehabilitation Act of 1973[53] did not include federal agencies within its scope at a time when its relevant language was identical to that of Title VI.[54] While the Rehabilitation Act was amended in 1978 to apply to federal agencies as well as to recipients of federal financial assistance,[55] Title VI has not been so amended and it thus appears that federal agencies at present are not formally subject to Title VI.

This is cause for concern as long as the equal protection principles embodied in the 5th Amendment, which would apply to federal agency action, require proof of purposeful (i.e., intentional) discrimination[56] while Title VI, applicable to the health care provider who must conform to those agency regulations, does not. If HCFA, as a condition of participation in a Medicare reimbursement program for heart transplantation, requires hospitals to adopt mandatory selection criteria, which would otherwise violate the Title VI effects test, a tangle of complex legal issues could arise. Questions of transplant facility liability may develop if federal regulations written by an agency not subject to Title VI contain patient selection criteria or methods which do not meet Title VI standards. The transplant facility could be faced with a costly discrimination suit or loss of federal funding if it elects to comply with the regulations; alternatively, it could be forced to forego participation in the heart transplant reimbursement program if it chooses not to risk noncompliance with Title VI.

While this dire scenario is unlikely to occur due to lack of enforcement and OCR's emphasis on voluntary compliance, it does point out the difficulty of enforcing Title VI in health programs which are regulated by federal agencies.[57] This problem may not arise if HCFA complies with a memorandum of understanding[58] between HCFA and OCR which was signed in 1979. Under the agreement HCFA has responsibility to:[59]

> . . . seek and select program policies and procedures which can assist in achieving affirmatively the object of the civil rights statutes . . . [to] take positive action to remove barriers that tend to exclude persons

> from the benefits of its programs because of race, color, national origin or handicap . . . [to] prevent discrimination before it occurs and to assist recipients of HCFA funds [to comply] with the civil rights authorities prior to the initiation of complaint investigations or other reviews by OCR.

Problems in establishing nondiscriminatory selection criteria and practices therefore should be of great interest to the Health Care Financing Administration despite the fact that it is outside of the direct scope of Title VI.

D. CONCLUSION

Transplant facilities, referring physicians, and government agencies such as HCFA each may take actions that can significantly affect minority access to medical care. This paper has explored the implications of Title VI of the Civil Rights Act of 1964 for these actions with respect to patient selection for heart transplantation. Although the unsettled nature of Title VI law in this area precludes the formation of definitive conclusions, it appears that Title VI may impose limitations on: (1) the permissible range of patient selection criteria; (2) physician and hospital referral practices; and (3) federal agency standard setting for provider inclusion in Medicare heart transplantation reimbursement plans.

As indicated above, choice and use of patient selection criteria may be circumscribed under Title VI if they result in discrimination against racial or ethnic minorities even if they were not intended to have that effect. These limits may apply to both the transplant facility and the referring physician. In addition, it may be advisable

for HCFA to assure that any standards for patient selection it may impose on transplant facilities as a condition of participation in a Medicare reimbursement program for heart transplantation do not conflict with the mandates of Title VI in order to avoid the creation of possible noncompliance issues for the transplant facility if not for HCFA itself.

Section 3 - AGE DISCRIMINATION IN PATIENT SELECTION FOR HEART TRANSPLANTATION

A. INTRODUCTION

The Health Care Financing Administration (HCFA) recently[1] solicited applications from hospitals and medical centers to participate in a general study to examine all aspects of heart transplantation. Included in the solicitation were the procedures and criteria to be used for selecting institutions to be reimbursed for heart transplantations under the study. The second of four criteria required that applicant institutions have adequate patient selection criteria, evidenced by (among others) criteria that give consideration to those factors that are recognized at the present as exerting an adverse influence on the outcome after cardiac transplantation. Such "strongly adverse factors" include:[2]

> [1] Advancing age--e.g., beyond the age (normally about 50) at which the individual begins to have a diminished capacity to withstand postoperative complications.

The purpose of this section is to examine, through the lens of the Age Discrimination Act of 1975 (ADA),[3] the legal viability of "advancing age" as a "strongly adverse factor" in the selection of patients for heart transplantation.

B. THE AGE DISCRIMINATION ACT OF 1975

The basic structure of the ADA is simple. The Act prohibits discrimination on the basis of age in all federally assisted programs and activities, and then excludes from coverage those programs or

activities "established under authority of any law" employing age criteria to condition benefits or participation. In addition, the statute contains several broadly worded "reasonableness" exceptions from the general prohibition. Finally, the Act requires each federal agency or department to issue implementing regulations. Enforcement of the ADA is to be through governmental agencies and departments and, following the 1978 amendments, by private individuals through the courts.

The ADA is expressly modeled upon Title VI of the Civil Rights Act of 1964,[4] which prohibits discrimination on the basis of race, color, or national origin in federally assisted programs. The prohibiting language of the ADA is nearly identical to that contained in Title VI, and to that in Title IX of the Education Act of 1972,[5] and Section 504 of the Rehabilitation Act of 1973.[6] In adding age to the list of protected characteristics (i.e., race, color, national origin, and handicap), Congress stressed that the ADA was intended to protect all persons at all ages, but it is clear that discrimination against the elderly was their primary concern.

Although enacted in 1975, the ADA has only very recently[7] been fully implemented and thus there is little case law interpreting its provisions. Depending upon these interpretations, the ADA may require major changes in the ways in which both public and private organizations conduct their activities. For example, then-DHEW (now DHHS) estimated that the ADA would apply to nearly 100,000 public and private entities that received federal financial assistance, including hospitals and schools.[8] The promise of its impact, however, may

never come to pass--while the ADA was based on an analogy between the prohibition of race and age discrimination, the prohibition was subject to such broad exclusions and exceptions that they may have deprived the Act of its intended effect.

1. DEFINING AGE DISCRIMINATION

The conceptual and practical difficulties of defining the boundaries of age discrimination are documented in detail elsewhere.[9] For present purposes it is sufficient to note that the Congressional formula in the ADA for proscribing the use of age distinctions is based to a large extent on a report on age discrimination prepared by the Civil Rights Commission.[10] The results of the Commission Report found their way into the language of the ADA and the regulations implementing the provisions of the statute.

a. The Commission Report. The Commission Report investigated the nature and extent of age discrimination in a wide variety of federal programs and federally assisted activities.[11] It began by setting down an extremely broad definition of age discrimination--"any act or failure to act, or any law or policy that adversely affects an individual on the basis of age."[12]

The definition used in the Commission Report is subject to at least three serious criticisms or flaws that have been used in arguing the extent of age discrimination. First, the statement lacks the basic requirement of a definition, that is, it places virtually no boundaries on the phenomenon defined. Using the Commission Report definition, virtually any action by any recipient of federal assistance would be seen to differentially affect age groups, and thus would

affect some of them adversely "on the basis of age." Second, the definition ignored the original language of the ADA and the exceptions it contained.[13] Finally, the definition assumes that age distinctions are, or should be considered in the same light as distinctions based on race or religion.

Given the constraints imposed by criticisms of its definition of age discrimination, the Commission Report concluded that in all the programs and activities that it studied: (1) age discrimination was widespread, (2) persons over the age of 65 were consistently adversely affected by the use of age distinctions, and (3) the administrative justifications for the use of age distinctions were not acceptable. The Commission Report recommended that, in order to expand the scope of the ADA, the statute's statement of purpose be amended to prohibit all age discrimination, not just that which was "unreasonable," and that the "reasonableness" exceptions and the "any law" exclusion be replaced with two other very narrow exceptions.[14]

Apparently on the basis of the Commission Report recommendations, Congress amended the ADA to delete the word "unreasonable" from the statement of purpose, but left intact the reasonableness standards contained in the exceptions. The task of reconciling these differences was left to HEW in the formulation of government-wide regulations for the implementation of the provisions of the ADA.

b. The Regulations. The overview of the regulations[15] states the general rule that "separate or different treatment that denies or limits service from or participation in a program receiving

Federal financial assistance will be prohibited . . ." More specific guidance about this prohibition is provided in the Rules Against Age Discrimination:[16]

> The rules stated in this section are limited by the exceptions contained in sections 90.14 ["normal operation" and "statutory objective" exceptions] and 90.15 ["reasonable factors other than age" exception] of these regulations.
>
> (a) General rule: No person in the United States shall on the basis of age, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any program or activity receiving Federal financial assistance.
>
> (b) Specific rules: A recipient may not, in any program or activity receiving Federal financial assistance, directly or through contractual, licensing or other arrangements, use age distinctions or take any other actions which have the affect, on the basis of age, of:
>
> (1) excluding individuals from, denying them the benefits of, or subjecting them to discrimination under, a program or activity receiving Federal financial assistance, or
>
> (2) Denying or limiting individuals in their opportunity to participate in any program or activity receiving Federal financial assistance.

The statement of the broad scope of coverage of the ADA contained in the overview of the regulations is considerably reduced by later regulatory provisions interpreting the statutory exceptions, and the exemptions dealing with employment practices,[17] affirmative action,[18] and special benefit programs.[19] The coverage of the ADA and its exceptions will be the focus of the remainder of this section.

2. THE COVERAGE OF THE ADA

The language of the ADA specifies that it applies to all "programs or activities receiving Federal financial assistance, including programs or activities receiving funds under the State and Local Assistance Act of 1972."[20] One important exclusion[21] and three exceptions may severely limit the scope of coverage of the ADA.

a. The "Any Law" Exclusion. Section 304(b)(2) of the ADA provides that:[22]

> The provisions of this title shall not apply to any program or activity established under authority of any law which (A) provides any benefits or assistance to persons based upon the age of such persons; or (B) establishes criteria for participation in age-related terms or describes intended beneficiaries or target groups in such terms.

The scope of this exclusion is extremely important in determining the applicability of the ADA because numerous federal, state, and local laws and regulations contain and regularly use age-based criteria.[23] Thus, beyond federal statutes, which are clearly excluded from coverage under the Act, what categories of "law" are included in the phrase "established under authority of any law"? Depending upon how this question is resolved, the ADA's scope could be extremely broad or quite narrow.

According to one authority,[24] the legislative history of the ADA, while bearing only indirectly on the question, suggests that the exclusion extends beyond federal law.[25] Considerations of practicality dictate the same result. Regulation of the exercise of the police powers--public health, morals, and safety--has traditionally

been reserved to the states, even though such regulations (as noted above) have often been based on age distinctions. Schuck argues[26] that it is unlikely that Congress intended to overrule the validity of these state and local laws, and only by excluding them from coverage under the ADA could such immunity be assured. The alternative interpretation, a more expanded coverage for the ADA, could result in the invalidation of literally hundreds of different state and local laws.

The only case testing the "any law" exclusion involved a federal statute that seems to necessarily require the use of age-related criteria because it related to retirement policy. In Seanor v. United States,[27] the plaintiff complained of a 5 percent reduction in his civil service annuity under the provisions of the Civil Service Retirement Act that required a reduction of benefits for those retiring under the age of 60. As might be expected, the court of claims suggested that the age discrimination claim was "absurd."

Seanor is a good example of the type of law envisioned by the "any law" exclusion. Retirement benefits for those who choose to retire before the specified age should reflect the probable increased duration of payments by a reduction of the annuity benefit. The application of the exclusion to the variety of other statutes that use age distinctions is, however, problematic.

b. The "Reasonableness" Exceptions. Based on the underlying assumption that certain "reasonable" uses of age distinctions are valid, the ADA contains three major exceptions to the strict prohibition against age discrimination.[28] In turn, the reasonableness of these exceptions is based on a number of different

considerations, including: (1) the distinct practical advantages of using age as a classification criterion; (2) the apparent ability of the elderly to protect their own interests through the use of the political process;[29] (3) the demonstrated correlation between age and ability; (4) the widespread use of age as a criterion for measuring other characteristics that should not or cannot be measured directly; (5) the legitimate use of non-age factors that have age-related impacts; and (6) the existing legal and political sanctions against the use of arbitrary age distinctions.[30] The following material examines each of these three "reasonableness" exceptions in greater detail.

1) The "normal operation" exception. Section 304(b)(1)(A) of the ADA provides that it:[31]

> . . . shall not be a violation of any provision of this chapter, or of any regulation issued under this chapter, for any person to take any action otherwise prohibited by [this Act] if, in the program or activity involved--
> (A) such action reasonably takes into account age as a factor necessary to the normal operation . . . of such program or activity.

Although there is little legislative history to explain the exception, its language closely parallels that of the "bona fide occupational qualification" (BFOQ) exception from the Age Discrimination Employment Act of 1967 (ADEA)[32] and Title VII of the Civil Rights Act.[33] In general, the BFOQ exception permits the use of distinctions based on characteristics such as sex if they can be shown to be bona fide occupational qualifications.[34] In effect this means that all individuals possessing the characteristics (i.e., sex or age) can be

categorically excluded, even though specific individuals within the category may be qualified.

The "normal operation" exception, however, is not identical to the BFOQ. The ADA exception refers to an action that "reasonably takes into account age as a factor necessary to the normal operation" of a program or activity, while the BFOQ exception[35] requires that a qualification must be "reasonably necessary." Thus, under the ADA exception, a more rigid standard is set--age must be necessary to the normal operation of the program, not reasonably necessary as under the ADEA. In addition, both Title VII and the ADEA BFOQ provisions refer to "the normal operation of a particular business," while the ADA exception refers to "the normal operation . . . of such program or activity." This difference in language may reflect the fact that the ADEA and Title VII were primarily intended to operate in the private sector (i.e., business and employment) while the ADA was intended for federally assisted programs.

Although the BFOQ may only provide a limited analogy for the "normal operation" exception of ADA, it may be useful to see how the courts have developed a preliminary general approach to analyzing exceptions to anti-discrimination provisions. It should be emphasized that the legislative history of the ADA does not suggest that the ADEA should serve as a model for interpreting the exceptions and, as discussed below, there is considerable controversy over the extent to which the two statutes should be so interpreted.

Only a few cases[36] have addressed the BFOQ exception in the ADEA. In Usery v. Tamiami Trail Tours, Inc.,[37] the court stated two

elements of such a test in the business hiring context. Thus, the employer must: (1) bear the burden of proving that the age requirement is reasonably necessary to the essence of the business (i.e., must relate to "essential job functions"), and (2) prove that there is "reasonable cause, that is a factual basis, for believing that all or substantially all persons [above the specified age limit] would be unable to perform safely and efficiently . . . , or [that] it is impossible or impractical to deal [with individuals over the specified age limit] on an individualized basis."[38]

If applied in the context of challenge to the age criterion employed in patient selection for heart transplantation, the program would face a similar task of justifying its use. First, the program would have to demonstrate that the use of the age criterion was essential to the operation of the program; the criterion must go to the essence of the program itself. In the context of heart transplantation, the meaning of the "essence of the program" is unclear. It is obvious that the essence of such a program is to perform heart transplants; it is less obvious that a high success rate achieved through screening by age is essential to the program. Second, the program must be able to demonstrate either (1) that the generalization regarding the age criterion is true, or (2) that its validity as applied to specific individuals would be impossible or impractical to test. The truth of the generalization and the problems of assessing its validity would likely have to be shown through risk assessments based on statistical evidence of lowered survivability of the aged following surgery.

The essential question here is whether the "normal operation" exception applies to a heart transplant program that uses an age criterion in order to target its scarce resources on those individuals who are most likely to maximize the benefits of the program, i.e., including the important social benefits that accrue from a longer, productive life. The regulations[39] provide little guidance in terms of access to health care. They do, however, suggest that medical schools cannot legitimately consider age in selecting students, even though achieving a high average longevity of medical practice may be an admirable goal. The only reason for this conclusion, according to the regulations, is that a medical school's basic objective is to train competent physicians, and this objective is not impaired if the duration of its graduates' practices is reduced. The regulations go on to note that "the 'normal operation' exception is not intended to permit a recipient program to use broad notions of efficiency or cost-benefit analysis to justify exclusion from a program on the basis of age."[40] Thus, if a basic objective of a heart transplant program is to maximize the expected benefit of increased survival, the "normal operation" exception may not be available to protect age-related patient selection criteria.

2) The "statutory objective" exception. The ADA provides a second exception from the general prohibition on age discrimination for any action that "reasonably takes into account age as a factor necessary . . . to the achievement of any statutory objective of" a program or activity.[41] Other than a reference in a conference report that the exception was added to clarify congressional intent,

there is no legislative history to explain how the exception was to be applied.

Schuck[42] argues that the language was intended to legitimate activities that may have been prohibited even in light of the "normal operation" exception. Thus, many federal statutes require the use of age-related policies, but do not specify which particular groups should receive the benefits of the statutes; and in pursuit of the statutory objectives, an agency may target program benefits on particular age groups, reflecting the agency's best judgment about how to accomplish statutory goals. For instance, most compensatory and special education programs are conducted for the benefit of children in elementary schools, in spite of the fact that nothing in the enabling statutes requires the programs to be so limited.

Schuck also asserts that the exception was intended to permit program administrators to employ age distinctions based on cost-benefit analyses in order to expend scarce program resources on those groups most likely to maximize the benefits of the program, even though such a procedure will often (as in the case of heart transplantations) exclude the elderly from participation. However, the legislative history of the ADA contains language that expressly contradicts this assertion. Thus, in commenting on the 1978 amendments, Representative Claude Pepper noted that:[43]

> The ADA must be viewed as a civil rights statute. As such, exceptions to it must be narrowly construed. I am particularly concerned with certain excuses for not serving older people. . . . They include the so-called cost-effectiveness argument, which asserts that, since it is often more expensive to reach older clients, a program could reasonably conclude that it could

> concentrate on younger persons. . . . [But] these excuses are nothing more than that. The deletion of the word "reasonable" from the [Act's] statement of purpose makes that clear. Such practices are discriminatory. They will be prohibited under the new amendments.

In regulations interpreting both the "normal operation" and the "statutory objective" exceptions to the ADA, then-HEW specified a four part test that the user of an age distinction must satisfy in order to be able to successfully invoke the protection of the exceptions.[44] The test provides that an action reasonably takes into account age as a factor necessary to the normal operation or the achievement of any statutory objective of a program or activity, if:

> (1) age is used as a measure or approximation of one or more other characteristics; and
>
> (2) the other characteristic(s) must be measured or approximated in order for the normal operation, or to achieve any statutory objective of the program or activity; and
>
> (3) the other characteristic(s) can be reasonably measured or approximated by the use of age; and
>
> (4) the other characteristic(s) are impractical to measure directly on an individual basis.

Thus, the regulations impose a heavier burden than mere rationality to exempt an action from the general prohibitions of the ADA. This level of stringency may be justified on the grounds that the ADA condones age distinctions only if they are necessary to the normal operation or achievement of a statutory objective of a program or activity (rather than "reasonably necessary" under the ADEA).

3) The "reasonable factors other than age" exception. The third exception to the ADA does not strictly concern age distinctions,

but is rather focused on the use of non-age factors. Thus, Section 304(b)(1)(B) provides an exception for otherwise prohibited activity "if, in the program or activity involved, . . . the differentiation made by such action is based upon reasonable factors other than age."[45] Although there is no legislative history dealing with this language, it is again similar to a statutory exception contained in the ADEA.[46]

The Supreme Court recently ruled that,[47] in the absence of provable discriminatory intent, the use of facially neutral factors that discriminate against particular groups is constitutionally valid. The "reasonable factors other than age" exception to the ADA may be construed as extending this constitutional principle to the statutory realm.[48]

Neither the statute, the regulations, nor the courts have provided any guidance as to what factors other than age may be considered under the ADA. The Department of Labor has issued regulations under the ADEA that permit the use of factors such as physical fitness, productivity, educational level, and performance on validated employment tests.[49] These factors are reasonable, however, only so long as they are job-related and are applied on an individual basis rather than on the basis of classes of individuals.

In a similar fashion, the government-wide regulations under the ADA construe the exception quite narrowly. They require that in order to be sustained, a non-age factor must bear a "direct and substantial relationship" to the normal operation of a program or

activity or to the achievement of a statutory objective.[50] In explaining this standard, the Rules state that:[51]

> The regulations adopt the "direct and substantial" standard because it provides the appropriate flexibility and, at the same time, avoids the weaknesses inherent in the "rational" standard. Use of the "direct and substantial" standard means that use of factors other than age must be carefully examined in light of the individual facts and circumstances surrounding their use. This examination will determine whether the use of the factor other than age is a sufficiently effective method of achieving a worthwhile program purpose to justify limiting or denying services or participation to adversely affect persons.

In addition, the direct and substantial:[52]

> . . . relationship requires the use of a standard of careful review and examination of uses of factors other than age on a case-by-case basis. . . . To use a rational relationship or minimum scrutiny standard would leave open the possibility of purposely circumventing the ADA by allowing administrators to use factors other than age to operate a program when an explicit use of age would be prohibited.

As in the case with the other provisions of the ADA, few cases have interpreted the "reasonable factors other than age" exception. In NAACP v. Wilmington Medical Center,[53] the court addressed the application of the ADA to a plan to relocate a major portion of the Wilmington Medical Center from its urban to a suburban location. It concluded that the "reasonable factor other than age" exception justified the hospital's action, even in the face of a less discriminatory feasible alternative. The court noted that:[54]

> . . . where the defendant actually adduces some evidence showing that he based his action upon a nonage-related factor that meets the criteria set out in the act and the regulations, he need not also adduce evidence

> showing that his action was the least discriminatory alternative. This interpretation is in accord with the congressional intent to apply a lesser degree of scrutiny to actions resulting in age discrimination than to those resulting in racial discrimination. Congress intended only to prohibit "unreasonable age discrimination."

Although not addressing the issue of equal access to health care, the NAACP decision suggests that the courts will give considerable deference to defendants in interpreting the "reasonableness" of factors other than age.

C. LEGAL VIABILITY OF AGE AS A PATIENT SELECTION CRITERIA

Because of both the lack of precision in its legislative history and the paucity of judicial experience with its interpretation, it is difficult to assess the extent to which the ADA may affect the use of age as a patient selection criterion. The controversies over the intended interpretation of the ADA remain to be resolved. The importance of these controversies, however, lies in the fact that their resolution will determine the scope of application of the statute; to the extent that the exclusions and exceptions are broadly construed, the range of permissible uses of age distinctions will be constricted. At this point the best that can be done is to identify those issues upon which there is some consensus and to point out issues that remain unresolved. The material in the following section will briefly discuss some of these considerations in specific reference to the use of age as a patient selection criterion in heart transplantation programs.

1. DEFINING DISCRIMINATION

A question of fundamental importance is whether age is or should be considered in the same vein as race, sex, or religion, meriting special attention and protection in the law. The arguments on both sides of this question are presented elsewhere,[55] but it should be noted that there are persuasive legal and policy considerations from both perspectives.

In general, though, it is difficult to imagine any procedure for rationing limited program benefits among a large pool of applicants (a necessary condition for the current operation of a heart transplant program) that would not have differential age-related impacts. For example, a means test or fee schedule will certainly work to the detriment of the less affluent (i.e., the retired elderly). Age groups are not uniformly distributed geographically, thus location criteria will tend to favor age groups living in proximity to transplant centers (be they young or old). Finally, a first-come-first-served procedure will tend to favor those age groups who are most mobile and better informed, to the detriment of the elderly. The question remains, though, whether such differential age impacts are "discrimination" or merely inadvertent by-products of administrative convenience in the distribution of government benefits.

Even a cursory examination of the law reveals that age distinctions arise in numerous different contexts, where they are used as proxies for, or predictors of, many factors thought to be correlated with age.[56] All such classifications treat one age group differently than another and frequently exclude one or more age groups

from benefits altogether. In general, the reasonableness of any particular age classification will hinge on the consequences of using age as a proxy or a predictor in the specific context in which it is used. The legal viability of age distinctions in patient selection for heart transplantation, however, will depend upon the resolution of as yet undecided questions about the scope of the ADA.

2. "ANY LAW" EXCLUSION

The courts have yet to determine whether the provisions of the ADA apply only to federal law or also encompass state and local law. It seems unlikely, however, that the courts would permit (or Congress intended) the ADA to be used to invalidate the myriad of legitimate uses of age distinctions in state and local law. In any case, regulations established under the authority of the federal Medicare program would be exempt from the ADA under the "any law" exclusion of Section 304(b)(2). Thus, it is likely that a strict age criterion for heart transplantation patient selection would be excluded from scrutiny under the ADA.

3. "NORMAL OPERATION" EXCEPTION

For an action such as the use of a strict age criterion to be sustained under the normal operation exception, there are two operative questions: (1) does the criterion "reasonably" take age into account? and (2) is the use of the age criterion "necessary" to the normal operation of a heart transplant program?

The first leg of the test may be satisfied merely by a showing that age is in some way correlated with physical hardiness or survivability. Under analogous tests of reasonableness, this

requirement could be met upon a showing of only the most minimal relationship between age and survivability; the use of the criterion would be unreasonable only if there was no relationship between the two.

The second leg of the test, however, is more difficult to meet. The question is whether the use of an age criterion is "necessary" to the normal operation of a heart transplant program. In the first instance, it should be apparent that an age criterion is not necessary to the normal operation of a heart transplant program--transplanting 60-year-olds would merely reduce the success rate of the program. The more appropriate question is whether an age criterion is "necessary" to the cost-effective operation of the program; that is, does the normal operation of a heart transplant program encompass targeting scarce resources on those individuals who are most likely to benefit from the program? The answer is not entirely clear, but there is language in the regulations that suggests that notions of efficiency and cost-benefit favorability cannot be equated with "necessary," and thus a strict age criterion may not meet this leg of the exception.

4. "STATUTORY OBJECTIVE" EXCEPTION

A strict age criterion in patient selection may be exempt from the provisions of the ADA if its use is necessary to "the achievement of any statutory objective" of a heart transplant program. Although the exact nature of a statutory objective is unclear, the regulations specify a four-part test for the exception. Thus, in order for a strict age criterion to be exempt under the statutory objective exception it must be shown that:

1) age is used as a measure or approximation of survivability;

2) survivability is an important factor for the normal operation, or the achievement of a statutory objective of the heart transplantation program;

3) survivability can be reasonably measured or approximated by the use of a strict age criterion; and

4) survivability is impractical to measure directly on an individual basis.

The burden of meeting these requirements will be placed on the transplant program asserting the need for using the strict age criterion.

D. CONCLUSION

With the caution that there is a woeful lack of law supporting any interpretation of the ADA, several tentative conclusions can be made:

1) Discrimination on the basis of age is not viewed with the same degree of alarm as discrimination on the basis of race, sex, or religion. In general, the use of age distinctions will be subject to fewer legal restrictions than other forms of discrimination.

2) Regardless of the ultimate determination of the meaning of "any law," the use of a strict age criterion in patient selection for heart transplantation will be excluded from the ADA's general prohibition against age discrimination.

3) Because the use of a strict age criterion is not "necessary" to the normal operation of a heart transplantation program, its use would not meet the requirements of the "normal operation" exception of the ADA.

4) If the relationship between age and survivability is demonstrably strong, the use of a strict age criterion will be exempt from the ADA under the "statutory objective" exception.

In summary, the ADA and its prohibition against age discrimination are unlikely to seriously impede the use of a strict age criterion in patient selection for heart transplantation.

Section 4 - GOVERNMENTAL REGULATION OF HEART TRANSPLANTATION AND THE RIGHT OF PRIVACY

A. INTRODUCTION

Many have argued that individuals have a right to choose to undergo various forms of medical treatment in accordance with their best judgment and wishes. In constitutional analysis, the ability of the individual to decide what experiences to undergo is commonly referred to as the right of personal autonomy, one aspect of the constitutionally based right to privacy.[1] The central theme of this right is the individual's freedom to make personal decisions so long as they do not adversely affect others. Its philosophical underpinnings are credited variously to Locke, Rousseau, and the authors of the Declaration of Independence.[2]

The question addressed in this section is whether the Supreme Court's personal autonomy doctrine could encompass an individual's independent decision, with the advice of a physician, to undergo a medical therapy or procedure such as heart transplantation. In claiming this right, the individual would be claiming the right to be free from unwarranted government intervention and regulation in his or her treatment decision rather than the right to receive resources sufficient to enable the patient active assistance to obtain the treatment. Like the right to decide whether to bear a child, any constitutional right to choose a method of treatment would be a right to be free from governmental interference or restriction, and not an entitlement to public resources.[3]

B. IS THERE A FUNDAMENTAL RIGHT TO CHOOSE A METHOD OF TREATMENT?

If the right to decide to undergo medical treatment was recognized as fundamental, all government regulation of health care decision-making would not be disallowed. No "right" is absolute; all are subject to limitations when their exercise conflicts with other sufficiently weighty interests. In essence, the right would mean that, absent government restriction, the individual would be free to effectuate his or her decision to undergo a particular form of treatment, and that only certain government restrictions would be valid. Thus, if recognized, a right to choose a method of treatment must yield to overriding public interests, just as the woman's right to choose whether to beget a child can be circumscribed when state interests in the life of the fetus and maternal health become sufficiently strong.[4]

While its exercise can be circumscribed, the significance of a right lies in the test that is applied to determine the validity of government actions restricting that right. In other words, the importance of a right lies in the degree of harm to other state concerns that must exist before that right can be limited. The government has broad powers to curtail individual freedom of action in order to promote legitimate state concerns, except where there is a "fundamental right" involved. Since the Supreme Court's rejection of "substantive due process"[5] protection of economic and property rights in the mid to late 1930's, the Court will actively protect only fundamental constitutional rights from unduly burdensome government action. Fundamental rights are those found within the text of the

Constitution or its amendments, or those that reflect values found by the Court to be fundamental to freedom in American society but are not found within the text of the constitution itself. The most significant of these non-textual fundamental rights recognized by the Supreme Court are the right of freedom of association, the right of privacy, and the right to vote.

The significance of a fundamental right lies in the level of justification that the state must assert to circumscribe it. When a governmental enactment is challenged, it is generally presumed valid. Unless a fundamental right is involved, the challenger has the burden of establishing that the law has no rational relation to a legitimate end of government, such as improving health, safety, welfare, or morals. As long as there is any conceivable basis for finding such a rational relationship, the law will be upheld. Only where a law is a totally arbitrary deprivation of liberty will it violate the due process clauses of the Fifth or Fourteenth Amendments to the Constitution.[6] This test of the validity of governmental action is commonly termed the "rational basis test."

Governmental impingement on fundamental rights, on the other hand, must satisfy a higher standard of validity. First, the government, rather than the challenger, has the burden of showing the need for the law. Second, only those needs that are "substantial," "compelling," or "overriding" will be upheld.[7] Third, the law must be carefully tailored by the government to limit the constitutional right only to the extent necessary to effectuate its overriding interest. In short, impingement of a fundamental constitutional right initiates a stricter

scrutiny both of the government's goals and the means by which it seeks to accomplish them. This more rigid standard is commonly referred to as the "strict scrutiny test."

Governmentally imposed burdens on individuals that would pass judicial review under the rational basis test often will not meet the more rigorous requirements of the strict scrutiny test. Thus, anchoring the decision to choose a particular method of treatment to a fundamental right in the Constitution is of great significance to attempts to regulate health care delivery. Without a constitutional foothold, a legislative determination that an individual's choice of treatment imposes burdens on other persons that justify restrictions will be readily accepted by the courts, and could leave the government with far more latitude to regulate the availability and performance of certain surgical and medical techniques, such as heart transplantation.[8]

However, if freedom to choose a particular method of treatment is considered a fundamental right, then state restrictions on that freedom will be less easily imposed because they will have to meet a heavier burden of justification (one that, in many cases, may not be demonstrable). Restrictions may still be imposed, but only where there is a clear necessity for them, with all doubts resolved in favor of the individual's right to choose treatment. Clearly there are costs to the government here in terms of limitations on its ability to regulate in areas in which it may have some interest. But these costs would be justified on the grounds that they would be less onerous than

the loss of the individual's personal autonomy in an area as vital as health care.

Given the high value that American society has placed on both personal autonomy and bodily integrity, it is not surprising that a constitutional right to choose to undergo particular forms of medical treatment is now being urged upon the courts. While the Supreme Court has never directly faced the question, the constitutional doctrine it has developed under the label of the right to privacy could furnish a foothold for such a right. The remainder of this section analyzes the privacy cases as a potential source of a constitutional right to decide to undergo a particular method of treatment.

1. THE RIGHT OF PRIVACY

Arguments in favor of a constitutional right to decide to pursue a particular form of medical treatment rely on the concept of constitutionally protected decisional privacy. Because the privacy doctrine formed the basis for the Supreme Court's ruling in Roe v. Wade,[9] protecting the woman's abortion decision, an area involving medical practice, it could be argued that it established a zone of privacy around personal health care decisions. In fact, several lower courts faced with legislation prohibiting the use of laetrile viewed the Roe decision exactly in this way. A careful reading of Supreme Court case law, however, leads to a rejection of this interpretation.

While Roe established the principle that a woman's decision to undergo an abortion is constitutionally protected, the Supreme Court decided the case on the basis of a woman's right to decide whether to beget a child, not on the basis of a right to make personal

decisions relating to health care. Similarly, the cases that established the right to use contraceptives -- Griswold v. Connecticut[10] and Eisenstadt v. Baird[11] -- found the use of birth control to be protected by both the privacy of the marital relationship and by the privacy of the decision to bear a child, and not by a privacy right to choose a particular form of medical treatment, or a right to do with one's body as one chooses. The identification of the right to choose a specific form of health care, therefore, does not automatically flow from the abortion or contraception cases.[12]

Nonetheless, such a right may be a logical extension of existing Supreme Court case law. Whether the right to make such decisions will be accorded constitutional protection by the Supreme Court depends on whether the autonomy/privacy rationale recognized in the existing case law will be confined to the areas of procreation and family relationships, or will assume broader dimensions. The next section explores the developing line of privacy case law in order to determine whether it will, or should, be extended to the right of an individual to choose to undergo a particular form of medical treatment.

a. Development of the Constitutional Right of Privacy. As was noted earlier, the Supreme Court grants special protection to those individual rights that it classifies as fundamental, and has so classified the "right of privacy." This right was first acknowledged by the Court in 1965 in its opinion in Griswold v. Connecticut,[13] where it held that a Connecticut statute that prohibited the use of contraceptives was unconstitutional on the basis that the statute impinged upon the privacy surrounding the marital relationship. While

such a marital privacy right is not explicitly set out in the Constitution, Justice Douglas found sufficient justification in the penumbra of the guarantees of the Bill of Rights to subject the challenged statute to strict scrutiny.[14]

Griswold's protection was extended to an unmarried person's right to use contraceptives in the 1972 case of Eisenstadt v. Baird.[15] With the decision in Baird resting on equal protection, rather than substantive due process grounds, the Court's explanation of the Griswold decision shifted from its previous emphasis on the narrow protection of the marital relationship to a broader protection of the autonomy rights of the individual.[16] This is significant to the medical treatment question because it is the more broadly based notion of personal autonomy that could encompass the vital decisions involved in personal health care decision-making.

Still within the context of procreation, the Court in Roe v. Wade[17] further developed the privacy right to include a woman's decision to terminate her pregnancy.[18] Expansion of the Griswold privacy right was justified on the basis of the significant impact on the lifestyle of the woman that could result if she were denied the option of having an abortion.[19] It is important to note, however, that Justice Blackmun stated that the Court's expansion of the privacy right did not create "an unlimited right to do with one's body as one pleases."[20] The Court recognized that there were significant state interests that justified regulation of some aspects of activities protected by the privacy right. The Court specifically recognized two such interests in the abortion context: protection of the health of

the pregnant woman, and protection of potential life. Noting that these interests became more significant as pregnancy progressed, the Court allowed increasing, though narrowly drawn, state regulation consistent with those interests.[21]

While Griswold and Wade are the most oft-cited "privacy" decisions, the most expansive definition of the privacy right appears in dicta in Whalen v. Roe.[22] There the Court stated that there are two types of interests embraced within the right of "privacy"-- (1) an individual interest in avoiding disclosure of personal matters, and (2) the interest in independence in making certain kinds of important decisions. It is the explicit articulation of the latter interest that could portend judicial recognition of the right to decide to undergo a particular form of medical treatment, for, as one U.S. District Court Judge reasoned, the decision to obtain or reject medical treatment is "both personal and important enough to be encompassed by the right of privacy."[23]

It is important to keep in mind that the Supreme Court's decisions dealing with the privacy right do not establish that personal health care decisions are entitled to the constitutional protection accorded to other recognized privacy interests, particularly those centered around childbearing and the family. Indeed, the Court has never been squarely faced with the issue. Nevertheless, the interest of an individual in independently making important decisions about the care of his or her health and person has been considered by the state and lower federal courts in at least two different circumstances: (1) where the individual refuses to undergo

treatment, and (2) where an individual wishes to choose a form of treatment that is outside the mainstream of conventional health care. These cases are instructive regarding the extent to which lower courts are willing to recognize a privacy right in the treatment decision context, and are reviewed, in turn, below.

b. Possible Directions for a Right of Privacy. Although the U.S. Supreme Court has not ruled on whether an individual has a constitutionally protected right to refuse lifesaving medical treatment,[24] the right to refuse medical treatment has been considered by several state and lower federal courts and, where recognized, has often been grounded in the privacy right. The significance of this line of cases is that they, like the unconventional therapy cases that follow, provide direct insight into the willingness of the courts to accord constitutional protection to personal health care decision-making autonomy. While they discuss a different aspect of the decisional right--the right to reject, rather than the right to seek out--they nevertheless are of direct relevance, for they are based on the same notion of a right to make important decisions relating to health care free from undue state interference.

In the first cases arising in the state courts, the right to decline medical treatment was based on religious objections to blood transfusions and operations.[25] Later cases relied upon the right of privacy rationale as well. All of these cases, however, seem to recognize that the right to refuse treatment is not absolute. Generally, the courts have considered two state interests when determining whether the individual can refuse treatment in specific

instances: (1) whether the patient has minor children who would become wards of the state if the individual should die,[26] and (2) whether public health would be endangered if treatment were not administered.[27] Absent the existence of these factors, however, the courts have generally taken the position that competent adults may refuse medical care, even if doing so is substantially certain to lead to death.[28]

While complicated by the introduction of a comatose, and therefore incompetent subject, one of the most explicit recognitions of the right to refuse to undergo treatment was Matter of Quinlan.[29] While recognizing that the state has a legitimate interest in protecting the health of the individual, the Quinlan Court reasoned that "the State's interest weakens, and the individual's right of privacy grows as the degree of bodily invasion increases and the prognosis dims."[30] Determining that Karen Quinlan's chances of recovery were virtually non-existent, and the bodily invasion great, the Court found that the right to choose termination of treatment, recognized as an aspect of the privacy right, outweighed the state's interest in protecting life.

As a result of the growing recognition of the right to refuse treatment, some commentators have argued that the privacy right also encompasses the right to decide to undergo unconventional forms of therapy. The cases supporting this argument have involved a series of challenges to both federal and state regulation or prohibition of the administration or disbursement of drugs or medical therapies of questioned efficacy or safety. While we do not intend to equate heart

transplantation to these forms of therapy, these cases nevertheless illustrate the type of approach that the courts may take if called upon to adjudicate a dispute over a heart transplantation regulation.[31]

The leading privacy challenge to a federal regulation, Rutherford v. United States,[32] began when a number of terminally ill cancer patients sought to enjoin the federal government from interfering with their access to laetrile. The district court adopted an expansive view of the right of choice of treatment, granting a terminal cancer victim temporary injunctive relief against enforcement of a Federal Food and Drug Administration (FDA) ban on the introduction of laetrile into interstate commerce. The court held that choice of treatment was an aspect of the plaintiff's right of privacy, and found that FDA procedures requiring the submission of proof of the safety and efficacy of a drug prior to its use did not withstand strict scrutiny.[33] On appeal, the circuit court declined to consider the constitutional issue of whether the plaintiff's right of privacy had been violated by the FDA efficacy requirement[34] and sustained the district court's opinion on statutory grounds.[35] On remand, the district court again asserted its position that enforcement of the laetrile ban by the FDA was an infringement of the patient's right of privacy and made permanent the injunction barring the agency from preventing the introduction of the drug laetrile into interstate commerce.

On appeal, the Tenth Circuit Court once again affirmed the district court, again on different grounds.[36] The issue presented

to the court was "whether the plaintiffs, a class of terminally ill cancer patients, should be allowed to acquire Laetrile for their own use intravenously despite the (Federal Food, Drug and Cosmetic) Act's requirements that 'safety' and 'effectiveness' be established for the approval of a 'new drug.'"[37] The court concluded that, as a matter of law, the terms "safety" and "effectiveness" as used in the statute "have no reasonable application to terminally ill cancer patients, and have no established meaning when considered in that context."[38] Because the regulations were invalidated on statutory grounds, the constitutional argument was once again not addressed.[39]

The Supreme Court took issue with the circuit court's characterization of the safety and efficacy requirements as meaningless when applied to terminal patients, and reversed and remanded the case.[40] It found "no license to depart from the plain language of the Act, for Congress reasonably could have intended to shield terminal patients from ineffectual or unsafe drugs."[41] The Court accepted FDA testimony from the laetrile hearings concerning the difficulty of identifying the terminally ill "except in retrospect."[42] It also accepted the FDA finding that a drug is effective if it fulfills claims of prolonged life, improved physical condition, or reduced pain.[43] But it specifically refused to address the privacy and the grandfather clause questions addressed at the district court level,[44] and remanded the case to the circuit court for further consideration of those issues.[45]

In a brief opinion,[46] the Tenth Circuit Court reversed the district court's holdings on both the grandfathering of laetrile and,

apparently, on the existence of the fundamental right to choose a particular method of treatment. The latter issue, however, was alluded to only briefly:[47]

> It is apparent in the context with which we are here concerned that the decision by the patient whether to have a treatment or not is a protected right, but his selection of a particular treatment, or at least a medication, is within the area of governmental interest in protecting public health. The premarketing requirement of the Federal Food Drug and Cosmetic Act . . . is an exercise of Congressional authority to limit the patient's choice of medication.

The Supreme Court denied certiorari.[48] While the quoted statement from the final Rutherford circuit court opinion is rather confusing, it signals, at minimum, a willingness to accord the government relatively wide latitude in regulating the availability of certain drugs, if not other forms of therapy. One federal district court took a similar position in an earlier case involving laetrile therapy.[49] The deciding judge stated that "(t)he outer limits of the right to privacy have not yet been determined, but I am satisfied that the right of a cancer patient to choose laetrile therapy does not fall within its perimeter."[50]

Another federal district court, however, has recognized a constitutionally protected right to decide to undergo particular forms of treatment, and as a result rejected as overbroad an attempt by the Texas legislature to regulate the administration of acupuncture. In Andrews v. Ballard,[51] the U.S. District Court of the Southern District of Texas held that the right to decide to undergo treatment is among those personal rights deemed fundamental and that the Texas

Medical Practice Act unconstitutionally interfered with the patient's right of privacy.[52] Andrews was a class action involving 46 plaintiffs who challenged the constitutionality of several articles of the Texas Medical Practice Act[53] as they applied to acupuncture, as well as certain rules of the Texas State Board of Medical Examiners.[54] The statutes generally provided that only a licensed physician may practice acupuncture. Unlike the other state statutes discussed in this section,[55] the Texas Act did not amount to a ban, but rather merely sought to regulate the practice of acupuncture. Nevertheless, the plaintiffs argued that their access to the procedure had been virtually eliminated by the physicians-only requirement.[56] Further, they argued that the regulations regarding acupuncture were overly broad and unnecessary to serve the state's interest in protecting the health and safety of its residents.[57]

Examining the cases where the Supreme Court has discussed the fundamental right of privacy, Judge McDonald noted that they generally involved "important" and "personal" decisions. She reasoned that the decision to undergo a medical procedure met those criteria;[58] the choice, she argued, is personal because it directly involves an individual's body,[59] and important because good health profoundly affects life.[60]

Although the court ultimately concluded that the right to privacy encompasses the treatment decision, it pointed out that state regulation in the area is not constitutionally proscribed. The state must prove that any regulations impinging on a fundamental right promote a compelling state interest and are as narrowly drawn as

possible.[61] The court found that the Texas Medical Practice Act authorized an overly broad and self-defeating intrusion on the individual's right to decide to undergo a particular form of medical treatment. While the court noted that the state had a compelling interest in assuring the safety and effectiveness of acupuncture,[62] and therefore could regulate its practice, it held that the Act's requirement that only physicians could perform this procedure was invalid because it was either unrelated to the legitimate health objectives of the state or insufficiently narrowly tailored.[63]

Thus, the federal courts have taken mixed views on the existence of the right to undergo a particular form of treatment. Several state courts, however, also have had the opportunity to address the issue, chiefly in the laetrile context.

The leading state court decision applying the right of privacy to the use of laetrile is People v. Privitera.[64] In that case, a physician and several other individuals were challenged with violating a California statute which made it a misdemeanor to provide any drug for the treatment of cancer unless it had been approved by either the FDA or the state board.[65] A California court of appeals reversed the defendant's convictions under the statute because, among other things, the statute infringed on the patient's fundamental right of privacy under both the California and the U.S. Constitutions.[66] The court of appeals rejected the state's claim that it had a sufficiently compelling interest to override the patient's right to decide to undergo laetrile treatments.[67]

The California Supreme Court reversed the decision over a strong dissent by Chief Justice Bird.[68] It held that the right to choose drugs of unproven efficacy is not encompassed by the right of privacy under either the U.S. or the California constitutions.[69] Failing to find the interest in independently deciding to undergo a particular treatment as included in the privacy right, the court subjected the California cancer drug statute to scrutiny under the less demanding rational basis test and upheld it. In so doing, the court announced that the bounds of the federal right of privacy had been set and included within them only "matters relating to marriage, procreation, contraception, family relationships, and child rearing and education."[70]

In contrast to the Privitera holding, several other courts considering the scope of the right of privacy have found it sufficiently broad to encompass the right to decide independently to acquire and use laetrile and other unapproved cancer drugs. In Suenram v. Society of Valley Hospital,[71] a New Jersey court recognized that the right of privacy extended to cover the personal health care choices of an informed, terminal cancer victim. In addition, a Florida court of appeals has held that a patient's voluntary and informed choice of a non-harmful treatment not endorsed by the medical profession fell within the zone of privacy guaranteed by the Florida constitution.[72] In dicta, the court also implied that the federal privacy right was also sufficiently broad to encompass such a decision.[73] In United States v. Evers,[74] a case involving an unapproved treatment for arteriosclerosis, the deciding

judge wrote of the patient's right, under the privacy doctrine, to receive medical care in accordance with his physician's best judgment.[75]

As the above cases illustrate, both the state and federal courts are divided in terms of their willingness to recognize the decisional right in the context of unapproved treatment. Because the cases discussing the right are few, and the cases finding such a right even fewer, it is difficult to speculate about which way the U.S. Supreme Court will rule on this issue.

FOOTNOTES

Section 1

1. 29 U.S.C. Section 794 (1976) (as amended by Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978, Pub. L. No. 95-602, Sections 119, 122, 92 Stat. 2955, 2982).

2. 29 U.S.C. Section 701-794 (1976) (as amended by Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978, Pub. L. No. 95-602, tits. I-IV, 92 Stat. 2955-3003).

3. See, 45 C.F.R. Section 84 et seq. (1979).

4. See, e.g., United States v. University Hospital, State University of New York at Stony Brook, No. C.V. 83-4818, (D.C. E.D.N.Y. Nov. 17, 1983).

5. Schroeder, Current Status of Heart Transplantation, 241 Journal of the American Medical Association 2069 (1979).

6. Penneck, Oyer, Reitz, Jamieson, Bieber, Wallwork, Stinson & Shumway, Cardiac Transplantation in Perspective for the Future: Survival, Complications, Rehabilitation and Cost, 83 Journal of Thoracic Cardiovascular Surgery 168 (1982) (Hereinafter cited as Penneck).et al., 1982.

7. Levy and Moskowitz, 1982.

8. Levy and Moskowitz, 1982. Of this amount, $20 billion represents health expenditures, $10 billion productivity lost due to illness, and $30 billion potential productivity lost due to early death. This $60 billion accounts for more than one-fifth of the total cause of illness in the United States.

9. For example, among heart transplant recipients, major causes of death include infection (58%), acute rejection (18.3%), graft arteriosclerosis (10.7%), and malignancy (4.6%). Penneck, cited supra n. 6. Infection, rejection and malignancy are all related to current methods of immunosuppression.

10. Christopherson, Heart Transplants, The Hastings Center Report 20, February 1982. There is already some evidence that the pressure of referrals is causing criteria other than expected outcome to be used for patient selection. Id. This pressure could conceivably result in more handicapped individuals being excluded from transplantation programs because of their perceived or actual limitations or because of the interviewers' personal biases.

11. Id. at 19.

12. See, Copeland & Stenson, Human Heart Transplantation, 4 Current Problems in Cardiology 1 (1979); Evans, Economic and Social Costs of Heart Transplantation, 1 Heart Transplantation 243 (1983).

13. Knox, Heart Transplants: To Pay or Not To Pay, 209 Science August 1, 1980, at 570, 572. Note that these psycho-social requirements, like the physical contraindications to heart transplantation, to the extent that they are currently valid, are subject to change as the technology of transplantation changes. For instance, improvements in transplantation may make continuous treatment unnecessary following a successful operation and therefore "cooperativeness" and ability to adjust to treatment may become less significant. See, Eschbach, Barnett, Daly, Cole and Schribner, Hemodialysis in the Home, 67 Annals of Internal Medicine 1167 (1967).

Environmental factors serve to exclude many from consideration. The cardiac patient may live in a rural area and thus never be referred to an urban transplant center. Inability to pay for treatment also results in the exclusion of many.

15. See Amos, "Transplantation-Opportunities and Problems," in Research in the Service of Man 177, 179; P. E. Oyer, E. B. Stinson, B. A. Reitz, et al., Cardiac Transplantation: 1980, 13 Transplantation Proceedings 199-206 (1981).

16. See, Karst, Equal Citizenship under the Fourteenth Amendment, 91 Harvard Law Review 610 (1977). For example, the language difficulties of hearing impaired persons are often assumed to be an indication of lack of intelligence. A. Crammate, Deaf Persons in Professional Employment (1968).

17. One of the most widely discussed allocation crises arose during the 1960's and early seventies, when the artificial kidney became a practical reality. At the Seattle Artificial Kidney Center at the University of Washington, explicit "social worth" distinctions were utilized to choose among medically suitable dialysis candidates. No moral or ethical guidelines were given the committee; the members were left to be guided by their individual consciences. The deliberations and criteria of the committee were as follows:

> All candidates for treatment must be under 40 years of age. They must be self supporting and residents of the state of Washington. A first panel, composed of physicians, eliminates the medically unfit . . . . These include heart patients, diabetics . . . and those with other chronic illnesses.

> The second panel consists of seven persons. At present they are a clergyman, a banker, a labor leader and two physicians. This group makes the final decision, and they remain anonymous in order to be protected from public pressures. . . .
>
> This civilian group bases its decisions on social and economic criteria. Other factors equal, the group chooses those with dependents. It favors patients who are stable in their behavior, and appear to be emotionally mature. To have a record of public service is a help--scout leader, Sunday school teacher, Red Cross volunteer. They frown on those who have a record of skipping appointments.

This type of "system" would result in the elimination of many handicapped individuals. For an interesting account of these early decisionmaking processes and some of the early legal arguments advanced against them, see, Sanders & Dukeminier, Medical Advance and Legal Lag: Hemodialysis and Kidney Transplantation, 15 U.C.L.A. Law Review 267 (1968).

Societal discomfort with these rationing choices may have been one major reason that federal legislation was soon enacted to provide almost universal funding for kidney dialysis. On July 1, 1973, Section 299-1 of the Social Security Amendments of 1972, termed H.R.-1, provided for the payment of maintenance hemodialysis and kidney transplantation for over 90 percent of the population. See, Friedman & Kountz, Impact of HR-1 on the Therapy of End Stage Uremia, 288 New England Journal of Medicine 1286 [1973] For an enlightening discussion of the political debate surrounding the enactment of HR-1, see, Rettig, The Policy Debate on Patient Care Financing for Victims of End Stage Renal Disease, 40 Law and Contemporary Problems 196 (1976).

18. This is because severe insulin requiring diabetes mellitus is exacerbated by the long-term use of immunosuppressive drugs, primarily steroids such as azatheoprine and prednisone.

19. 29 U.S.C. Section 794 (1976), (as amended by, Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978, Pub. L. No. 95-602, Section 119, 122, 92 Stat. 2955, 2982).

20. 45 C.F.R. Section 84 (1979).

21. Pursuant to Executive Order No. 11,914, 3 C.F.R. 117 (1977), reprinted in 29 U.S.C. 794 app., at 88 (1976). The Secretary also promulgated 45 C.F.R. Section 85 (1979) to coordinate enforcement of Section 504 with respect to all federal agencies and programs providing federal financial assistance. Each

federal agency must issue its own regulation enforcing Section 504. Executive Order No. 11,914, supra. See also, Rehabilitation, Comprehensive Services, and Developmental Disabilities Amendments of 1978, 29 U.S.C. 794 (1978). These regulations must be consistent with the standards and procedures established by HEW (now Health and Human Services (HHS). Executive Order No. 11,914, supra. Because of the supervisory authority granted to HHS, this article discusses primarily the HHS regulation.

22. The term "recipients" is defined to include those entities that receive the assistance from HHS, not the persons served by the programs; they are termed the "beneficiaries." Section 504 applies whether recipients receive assistance directly or through another recipient.

23. 42 U.S.C. Section 2000d-4 (1974) (Title VI). Although a comparable provision was not included in the Rehabilitation Act of 1973, the Secretary of HEW concluded that its omission was inadvertent. 42 Fed. Reg. 22,685 (1977). The Section 504 regulations are therefore similarly limited in application.

"Federal financial assistance" is defined in the HHS regulations as:

> any grant, loan, contract (other than a procurement contract or a contract of insurance or guaranty), or any other arrangement by which the Department provides or otherwise makes available assistance in the form of: (1) funds; (2) services of federal personnel; (3) real or personal property or any interest in or use of such property, including (i) transfers or leases of such property for less than fair market value or for reduced consideration; and (ii) proceeds from a subsequent transfer or lease of such property if the federal share of its fair market value is not returned to the Federal Government. 45 C.F.R. Section 84.3(h) (1979).

24. Medicare Part A provides reimbursement for inpatient hospital services and certain post-hospital extended care services and home health services for qualified individuals. 42 U.S.C. Section 1395c et seq. (1976).

25. Medicare Part B is the program of supplementary medical insurance benefits for the aged and disabled and provides reimbursement for physicians' services and other enumerated outpatient services for qualified individuals. 42 U.S.C. Section 1395j et seq. (1976).

26. See, e.g., Cook v. Ochsner Foundation Hospital, No. 70-1969(E.D. La., Memorandum and Order on Defendant's Motion to Dismiss entered Jan. 30, 1981), at 9.

27. 45 C.F.R. Section 84.51 (1979).

28. Historically, as noted in Katz and Capron, Catastrophic Diseases: Who Decides What? (1975) at 8-9 (hereinafter referred to as "Katz and Capron"), some leading surgeons felt strongly that the procedure was investigatory (and therefore should be carried out only on a limited scale). They dissuaded others from joining the cardiac transplantation sweepstakes of 1968-69. See also, F.D. Moore, Transplant: The Give and Take of Tissue Transplantation 255 (1972). In fact, in February, 1969, in light of poor survival rates and failure to resolve the rejection problem, an informal moratorium on heart transplantation was called. This is evidenced by the substantial decrease in the number of procedures performed. Worldwide there were two heart transplants performed in 1967, 101 in 1968, 47 in 1969, 17 in 1970, 17 in 1971, and 16 in 1972. More recently, however, as the survival rates of heart transplant recipients have approximated those for cadaver kidney transplant recipients, the therapeutic potential of heart transplantation is increasingly being recognized.

29. 45 C.F.R. Part 605, 47 Fed. Reg. 8570 (1982).

30. 47 Fed. Reg. 8570, (1982). [A qualified handicapped individual is one who . . .] "with respect to scientific and technical experimentation, observation or field work a person who meets the academic, scientific, and technical standards for admission and any reasonable physical qualifications for participation."

31. This in fact is the approach taken by the NSF regulations, supra, n. 25. While the NSF admits its recipients' obligation "to provide for the participation of handicapped persons who are qualified to participate in the research so designed," the NSF regulations provide that "factors such as costs, risk, or sacrifice of legitimate program objectives may be considered" when determining the reasonableness of any physical requirements.

32. 45 C.F.R. Section 84.3(j).

33. 45 C.F.R. Section 84.53.

34. While neither the Act nor the regulations list specific conditions considered to be handicaps, the departmental analysis accompanying the regulations notes that clearly included are such diseases and conditions as orthopedic, visual, speech and hearing impairments, cerebral palsy, epilepsy, muscular dystrophy, multiple sclerosis, cancer, heart disease, diabetes, mental retardation, and emotional illness.

35. HHS rejected the suggestion that it should limit coverage to the more common handicaps. Its position has been that the statutory language of Section 504 requires the expansive approach taken.

The regulations also include specific learning disabilities such as dyslexia and developmental aphasia.

36. It should be noted that environmental, economic, and cultural disadvantages are not in themselves considered handicaps within the meaning of Section 504. Characteristics such as homosexuality, age, or prison record are therefore not considered handicaps.

37. 442 U.S. 397 (1980). While Davis set forth these principles in the context of nursing home admissions, they appear to be equally applicable to all Section 504 cases involving admissions processes and standards since it defines "otherwise qualified," the critical term of the statute which applies in all settings.

38. With respect to health services, a qualified handicapped individual is one who meets the essential eligibility requirements for receipt of such services. 45 C.F.R. Section 84.3(k)(4).

39. 442 U.S. at 408.

40. 666 F.2d 761 (2d. Cir. 1981).

41. According to the opinion, the American Psychiatric Association's Diagnostic and Statistical Manual (3rd. Ed.) notes that a person suffering from this disability is likely to continue to have it through most of his or her adult life, subject to modification only by treatment by well trained therapists over a period of years and adoption of a lifestyle that avoids situations that subject the person to types of stress with which he or she cannot cope. 666 F.2d at 768.

42. 666 F.2d at 770.

43. Doe v. New York University, 442 F. Supp. 522 (S.D.N.Y. 1978).

44. Doe v. New York University, No. 77 Civ. 6285 (GLG) (slip opinion) (S.D.N.Y. Sept. 25, 1981 as amended October 2, 1981).

45. Id.

46. 666 F. 2d 761, 777 (1981). Before reaching the merits of the case, the court of appeals noted that there were two basic elements that needed to be demonstrated before a preliminary injunction could be issued. The first element, irreparable harm, was dispatched with quickly. The court found that a further delay in going back to school was insufficient harm to justify the issuance of a preliminary injunction. The second factor, likelihood of success on the merits, was also dismissed because the plaintiff had already entered NYU and the issue was relevant to motions for summary judgment.

47. 666 F. 2d at 776. (Emphasis added.)

48. See, H. K. Beecher, "Scarce Resources and Medical Advancement," in Ethical Aspects of Experimentation with Human Subjects, (1969).

49. Pushkin v. University of Colorado, 658 F.2d 1372, 1391 (10th Cir. 1981).

50. Some courts, however, are far more willing to defer to the opinions of the specialist. See note 68 infra.

51. 45 C.F.R. Section 84.52(a)(4).

52. Knox, Heart Transplants: To Pay or Not to Pay, 209 Science, August 1, 1980, at 570, 572.

53. The reader is cautioned that this discussion is made by analogy to the use of selection criteria in education and employment. Not surprisingly, the literature on handicap discrimination is simply devoid of discussion about patient selection. This section draws in particular on Gittler's discussion of the use of handicap-specific exclusionary criteria in employment contexts. See, Gittler, Fair Employment and the Handicapped: A Legal Perspective, 27 DePaul Law Review 953 (1978).

54. Id. See also the HHS regulations on employment, 45 C.F.R. Section 84.13(a): "A recipient may not make use of any employment selection criteria that screens out or tends to screen out handicapped persons or any class of handicapped persons unless (1) the . . . selection criterion, as used by the recipient, is shown to be job-related for the position in question, and (2) alternative job-related criteria that do not screen out or tend to screen out as many handicapped persons are not shown by the director to be available."

55. Epilepsy Foundation of America, Answers to the Most Frequently Asked Questions People Ask About Epilepsy, at 8-9 (1975), cited in Gittler, Fair Employment and the Handicapped: A Legal Perspective, 27 DePaul Law Review 953, 967 (1978).

56. Gittler, cited n. 53 infra, at 967.

57. Several lower courts have ruled that Section 504 bars employers from excluding the handicapped through use of blanket presumptions of incompetence. See, Duran v. City of Tampa, 451 F. Supp 954 (M.D. Fla. 1978). (Section 504 prohibits police department for disqualifying plaintiff for employment because he suffered from epilepsy during childhood); Gurmankin v. Costanzo, 411 F. Supp. 982 (E.D. Pa. 1976)(dictum), aff'd 556 F.2d 184 (3rd. Cir. 1977). Compare Davis v. Butcher, 451 F.Supp. 791 (E.D. Pa. 1978)(absolute exclusion of former drug

users for city employment violates Section 504) with New York Transit Co. v. Beazer, 440 U.S. 568 (1978) (transit authority policy of excluding participant in methadone maintenance programs from employment did not violate the Equal Protection clause or Title VII).

One must bear in mind, however, the definition of handicapped individual set out the the regulations; often, persons with slight handicaps are not handicapped within the meaning of the statute because such handicaps do not impinge on that person's ability to carry out major life functions. See 45 C.F.R. Section 84.3.

58. For a discussion of these principles in the employment setting, see Gittler, cited in n. 53 supra, at 978-80.

Since the Section 504 standard rests on an individualized assessment of performance capabilities, it does not involve the concept of "bona fide occupational qualification" (BFOQ). A BFOQ permits an employer an exemption from the general prohibition against policies that discriminate against a designated class and allows a policy that absolutely excludes all members of a protected class from a particular job regardless of any individual's qualifications or abilities. BFOQ provisions are contained in the Age Discrimination Act of 1967, 29 U.S.C. Section 623 (f)(1)(1970), and in Title VII, 42 U.S.C. Section 2000(e)(2)(1)(1970).

59. This example is offered merely to illustrate the analytical approach; it does not rest on any knowledge of the ability of diabetics to meet the essential eligibility requirements of a heart transplantation program.

60. OCR Memorandum, December 22, 1980; see also 45 C.F.R. Section 84.(b)(4): "A recipient may not . . . utilize criteria that have the effect of subjecting qualified handicapped persons to discrimination on the basis of handicap"; and Section 84.52(a)(4), "(A recipient may not) provide benefits or services in a manner that limits or has the effect of limiting participation of qualified handicapped persons."

61. OCR Memorandum, December 22, 1980. This test is adapted from Griggs v. Duke Power Co., 401 U.S. 424, 431 (1971) and Dothard v. Rawlinson, 433 U.S. 321 (1977). Under these cases, a plaintiff need only show that the facially neutral standards in question select applicants for hire in a significantly discriminatory pattern to establish a prima facie case of discrimination. Once it is thus shown that the standards are discriminatory in effect, the employer must meet the burden of showing that any given requirement has a manifest relation to the employment in question. If the employer proves that the

challenged requirements are job-related, the plaintiff may then show that other selection devices without a similar discriminatory effect would also serve the employer's legitimate interest in "efficient and trustworthy workmanship." See, Albermarle Paper Co. v. Moody, 442 U.S. at 425, quoting McDonnell Douglass Corp. v. Green, 411 U.S. 792, 801.

62. The burden shifting scheme in a case before the OCR places the same evidentiary burdens on the recipient as those enunciated in Griggs except that the recipient also must show that no selection devices with a lesser discriminatory effect are available. OCR Memorandum, December 22, 1980.

63. See discussion in the text accompanying n. 6.

64. Under the regulations, employers as well as educational institutions are required to make reasonable accommodations to the known physical or mental limitations of an otherwise qualified handicapped applicant or employee unless the recipient can demonstrate that the accommodation would impose an undue hardship on the operation of its program. Reasonable accommodation may include making facilities accessible to the handicapped, job restructuring, modified work schedules, provisions of readers, etc. See, 45 C.F.R. Section 84.12.

The extent of the recipient's duty to accommodate the handicapped has stirred much controversy. For a thorough discussion of the topic see, Note, Accommodating the Handicapped: Rehabilitating Section 504 After Southeastern, 80 Columbia Law Review 171 (1980).

65. See discussion, section 1.

66. Caution must be taken even with individualized interviews, however, for the interviewer may fail to apply the established standards, due to misconceptions about the individual's handicapping condition. See, for example, Pushkin v. University of Colorado, discussed infra at n. 68.

67. 45 C.F.R. Section 84.52(a),(b). This conclusion flows from the general notion that, in providing health services, a recipient may not "afford a qualified handicapped person an opportunity that is not equal to that offered by others." A determination based on unfounded factual conclusions would violate this provision. See also, Pushkin v. University of Colorado, 658 F.2d 1372 (10th. Cir. 1981).

68. 658 F.2d 1372 (10th. Cir. 1981).

69. Id. at 1386.

70. The district court also commented on the overall fairness of the graduate admissions program, and the difficulties involved in judicial second guessing of medical professionals. Even so, the court felt that Section 504's vindication rested on an active judicial role in reviewing discriminatory admissions decisions:

> "It is very difficult for a tyro to second guess psychiatrists about their judgments and by so doing rule that a handicapped person is qualified when they say he is not, but such is the office of Section 504." 504 F.Supp. 1292, 1299 (D.C. Dist. Colo. 1981), aff'd 658 F.2d 1372 (10th. Cir. 1981).

In determining whether an individual is "otherwise qualified" for admission, courts may exhibit a marked tendency to defer to evaluations made by the institution where the courts feel they are ill-equipped to themselves evaluate the future performance of the candidates. This, of course, will have a great deal of impact on the outcome of any litigation dealing with medical assessments because it is an area where courts have traditionally deferred to physicians' expertise. However, some courts appear much more willing than others to probe the bases for an expert committee's findings. A comparison of the approaches taken by the Tenth and Second Circuit Courts illustrates the varying level of judicial deference to the recipient's expertise. Both cases involved candidates for medical programs, and both institutions required the individual to be able to handle the considerable amount of stress involved in both the profession and the training. Yet, as indicated, the Tenth Circuit has shown itself much more willing to scrutinize carefully the actions of an admissions team of physicians than has the Second Circuit. Compare, Pushkin v. University of Colorado, 658 F.2d 1372 (10th. Cir. 1981) with Doe v. New York University, 666 F.2d 761 (2d. Cir. 1981).)

71. The Pushkin district court commented that subjective criteria are often "vague and impractical [and] . . . offer a convenient pretext to prejudice perhaps without a conscious effort by the decision maker." 504 F. Supp. at 1292.

While the court criticized reliance on unnamed criteria, it also noted that the use of such criteria is permissible under Regents of California v. Bakke, 438 U.S. 265 (1978).

72. 504 F. Supp. at 1299.

73. Id., aff'd, 658 F.2d 1371 (10th. Cir. 1981).

Section 2

1. Pub. L. No. 88-352, tit VI, Section 601-605, 78 Stat 752-53 (codified at 42 U.S.C. Sections 2000(a)-2000(d)4 (1970)).

2. The major sources of federal financial assistance to hospitals are funds received under the Hospital Survey and Construction Act (Hill-Burton Act), 42 U.S.C. Sections 291-290 (1976), as well as the Medicare and Medicaid programs.

3. For a discussion of this issue, see Wing, Title VI and Health Facilities: Forms without Substance, 30 Hastings Law Journal 145 (1978); and Chavkin, Health Access and the Civil Rights Laws: The Smoking Gun and Other Sorrows, 15 Clearinghouse Review 561-566 (Nov. 1981).

4. Evans, Health Care Technology and the Inevitability of Resource Allocation and Rationing Decisions: Notes of a Technology Watcher, Update No. 10, National Heart Transplantation Study, Battelle Human Affairs Research Centers, August 1982; Cooper, Rationing Health Care, London: Croom Helm Ltd., 1977; Golding, Tosey, The Case of High-technology Medicine, The Lancet, 195-197 (July 1980); Cochrane, Effectiveness and Efficiency: Random Reflections on the National Health Service, London: Nuffield Provincial Hospitals Trust, Burgess and Son, Ltd., 1971; Fuchs, Who Shall Live?: Health, Economics, and Social Choice, New York: Basic Books, 1974; and Weinstein and Stason, Foundations of Cost-effectiveness Analysis for Health and Medical Practices, 296 New England Journal of Medicine 716-721 (1977).

5. See, e.g., Aday, Achieving Equity of Access to the American Health Care System: An Empirical Look at Target Groups, in U.S. Commission on Civil Rights, Civil Rights Issues in Health Care Delivery (1981), p. 252; Institute of Medicine, Health Care in a Context of Civil Rights, National Academy Press: Washington, D.C., 1981, pp. 20-71; and DHEW, Health Status of Minorities and Low Income Groups, 1980, Pub. No. (HRA) 79-625.

6. The current availability of heart transplantation is somewhat similar to that of dialysis in the late 1960s and early 1970s before the extension of Medicare coverage for all End-Stage Renal Disease (ESRD) victims resulted in widespread availability of dialysis treatment. Heart transplantation is, as dialysis was then, both scarce and extremely financially burdensome for the individual. Evans, et al., Implications for Health Care Policy: A Social and Demographic Profile of Hemodialysis Patients in the United States, 245 Journal of the American Medical Association 487 (1981); see also, Evans, Defining the Need for Heart Transplantation, Update No. 5, National Heart Transplantation Study, Battelle Human Affairs Research Centers, 1982.

In the early years, the available data indicate that blacks were severely underrepresented in the dialysis population. The current dialysis care levels indicate that blacks suffer disproportionately from ESRD; although blacks in 1970 (U.S. Census) comprised only 11.3% of the U.S. population, as of 1977 blacks constituted 24.1% of the Medicare dialysis population. Despite the prevalence of ESRD among blacks, only 7% of the 1967 (pre-Medicare) dialysis population was black (Evans, "Implications for Health Care Policy," cited supra).

Due to the expense, differential access to health care, and possible biases in the selection procedures, as well as other factors, it is very likely that minorities are also underrepresented among the heart transplant recipient population, despite higher incidence of death due to cardiac diseases among blacks. Health, United States, 1981, DHHS Pub. No. (PHS) 82-1232.

7. A facially neutral practice is one that, while appearing nondiscriminatory on its face, will tend to exclude minority group members. For instance, some hospitals that participate in the Medicaid program require that patients be admitted by physicians with staff privileges. Minorities are less likely to have access to physicians with staff privileges than are whites in the same income groupings. Thus, the admission practice is one that tends to exclude minorities from treatment although it makes no reference to race. See, Ivie, Ending Discrimination in Health Care: A Dream Deferred, in Civil Rights Issues in Health Care Delivery, cited n. 5, supra, pp. 282-317.

8. The Supreme Court soon may address this issue in Guardians Association of NYPD, Inc. v. Civil Service Commission, 633 F.2d 232 (3d Cir. 1980), cert. granted 50 U.S.L.W. 3547 (U.S., Jan. 11, 1982 (no. 81-431).

9. See, e.g., Lau v. Nichols, 414 U.S. 563 (1974); Board of Education v. Califano, 584 F.2d 576 (2d Cir. 1978) (aff'd on other grounds sub nom Board of Education v. Harris, 444 U.S. 130 (1979).

10. See Resident Advisory Board v. Rizzo, 564 F.2d 126, 147-49 (3d Cir. 1977). See, generally, Perry, The Disproportionate Impact Theory and Racial Discrimination, 125 University of Pennsylvania Law Review 540, 544-48 (1977). As stated, the effects test is adopted under the HEW regulations implementing Title VI. The regulations prohibit discrimination that restricts an individual's enjoyment of any advantage or privilege enjoyed by others receiving any service, financial aid, or other benefit under the program. 45 C.F.R. Section 80.3(b)(3) (1979) (emphasis added). The regulations further state that a recipient may not, "in determining the types of services . . .

or other benefits which will be provided under such programs . . . or the class of individuals to be afforded an opportunity to participate in any such programs, directly or through contractual or other arrangements, utilize criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color, or national origin. . . ." Id. at Section 80.3(b)(2).

11. See, Village of Arlington Heights v. Metropolitan Hous. Dev. Corp., 429 U.S. 252 (1977); Washington v. Davis, 426 U.S. 229 (1976).

Several recent lower federal court decisions have required a showing of purposeful discrimination under Title VI. See Guardians Assn. of NYC Police Dept. Inc. v. Civil Service Commission, 633 F.2d 232 (3rd Cir. 1980) cert. granted 50 U.S.L.W. 3547 (U.S., Jan. 11, 1982)(no. 81-431); Lora v. Board of Education of New York, 603 F.2d 248 (2d Cir. 1980); Parent Assn. of Andrew Jackson High School v. Armback, 598 F.2d 705 (2d Cir. 1979).

However, the Supreme Court in the past has not required proof of discriminatory motive in Title VI cases. The Court in Lau v. Nichols based its decision on the government's power to establish the terms upon which it would disperse money. The Court cited Sen. Humphrey, quoting from Pres. Kennedy's message to Congress, June 19, 1963: "Simple justice requires that public funds, to which all taxpayers of all races contribute, not be spent in any fashion which encourages, entrenches, subsidizes, or results in racial discrimination." 414 U.S. at 569.

In Board of Education v. Califano, the Court reasoned that Congress has the power to enact stricter statutory standards than the constitutional minimum required by the 14th Amendment. The Supreme Court expressly declined to decide whether Title VI required a showing of discrimination or effectual discrimination. 444 U.S. at 149. Writing for the dissent, Justice Stewart relied on dicta in Regents of California v.Bakke, 438 U.S. 265, 281-87, 328-55 (1978) (Powell, J., at 281-87 and Brennan, White, Marshall & Blackman, JJ, at 228-55) to support his position that: "Title VI, which prohibits discrimination in federally funded programs, prohibits only discrimination violative of the 5th Amendment and the Equal Protection clause of the 14th." 444 U.S. at 160.

The Court in Bakke, however, did not overrule Lau and, in fact, cited it to support the position that Title VI embodies constitutional definitions of proscribed racial classifications. 438 U.S. at 284, 341, 350-51. Moreover, the Court was not deciding the type of discrimination proscribed by

Title VI; it was deciding whether Title VI prevented the use of all racial criteria.

More recently, the Court in Fullilove v. Klutznick, 448 U.S. 448 (1980) employed Lau to support its holding that federal law requiring that at least 10 percent of federal funds granted to states for local public works projects be allocated for minority businesses did not violate the Equal Protection clause of 14th Amendment or the Due Process clause of the 5th Amendment. The Court stated:

> There are relevant similarities between the MBE [Minority Business Enterprise) program and the federal spending program reviewed in Lau v. Nichols, 414 U.S. 563 (1974). In Lau, a language barrier "effectively foreclosed" non-English speaking Chinese pupils from access to the educational opportunities offered by the San Francisco public school system. Id at 564-66. It had not been shown that this had resulted from any discrimination, purposeful or otherwise, or from other unlawful acts. Nevertheless, we upheld the constitutionality of a federal regulation applicable to public school systems receiving federal funds that prohibited the utilization of criteria or methods of administration which have the effect of defeating or substantially impairing accomplishment of the objectives of the [educational] program as respect individuals of a particular race, color or national origin. Id at 568.

Several lower courts have found Lau to be controlling and have used the effects test in Title VI cases. See, e.g., Guadalupe Org. Inc. v. Tempe Elementary School District No. 3, 687 F.2d 1022, 1029 (n. 6). (9th Cir. 1978); Serna v. Portales Mun. Schools, 499 F.2d 1147, 1154 (10th Cir. 1974); Wade v. Mississippi Coop. Extension Serv., 528 F.2d 508 (5th Cir. 1976); Shanna v. HUD, 436 F.2d 809, 816-17 (3rd Cir. 1970); NAACP v. Medical Center Inc., 657 F.2d 1322, 1328-30 (3rd Cir. 1981); De La Cruz v. Tormey, 582 F.2d 45, 61 and n. 16 (9th Cir. 1978), cert denied 441 U.S. 965 (1979); Larry P. v. Riles, 495 F.Supp. 926, 964-5 (ND Cal 1979).

12. For a full discussion of these issues, see Institute of Medicine, Health Care in a Context of Civil Rights, National Academy Press (1981).

13. See Schwemm, Washington to Arlington Heights and Beyond: Discrimina- tory Purpose in Equal Protection Litigation, University of Illinois Law Review, 961, 974 (1977).

14. Various agencies of the federal government provide financial assistance and therefore administer aspects of Title VI. However, as stated, the principal agency with responsibility for health programs is the Department of Health and Human Services through the Office for Civil Rights.

15. Title VI establishes specific procedures for agencies to follow in enforcing the civil rights obligations of recipients. The enforcement process encompasses two basic procedures--complaint investigations and compliance reviews. Complaint investigations are initiated in response to specific complaints of discrimination filed by parties or their representatives. 45 C.F.R. Section 80.7(b). Compliance reviews are initiated by the OCR in order to monitor ongoing compliance and do not depend on the filing of a complaint. 45 C.F.R. Section 80.7(a).

16. Chavkin, cited n. 3, supra, p. 565.

17. The test was set forth in a memorandum in 1 OCR Policy Digest No. 2, at 10. For an example of an application of the effects test in a specific factual setting, see, OCR Memorandum to Carolyn Russell from David Chavkin dated December 11, 1980, 1 OCR Policy Digest.

While the Digest and the policy interpretations in it are approved before issuance by the Director of the Office of Civil Rights and by the Assistant General Council for Civil Rights as the official policy of the office, they are not subject to the notice and comment provisions of the Administrative Procedure Act, 5 U.S.C. Section 53(b), and are not strictly binding on the courts, National Nutritional Foods Assn. v. Weinberger, 512 F.2d 688 (2d Cir. 1975); National Assn. of U.S. Agents Inc. v. Bd. of Governors of Fed Reserve System, 489 F.2d 1268 (D.C. Cir. 1974). They are deferred to, however, in enforcement actions as the official position of the agency. See, e.g., Lau v. Nichols, 414 U.S. 563, 568 (1974).

18. OCR memorandum, cited n. 17, supra. One of the key issues that frequently arises in enforcement actions is which party bears the burden of persuasion on each of these elements. For example, must the OCR demonstrate the availability of alternatives or must the recipient demonstrate the absence of alternatives?

The OCR interpretive rules set forth OCR policy in this area as well. In applying the three-part test, the burden is on OCR to establish that the proposed action will have disproportionate, adverse effect. The burden is on the recipient to demonstrate that a legitimate objective would be furthered and that no alternative course of action could be adopted that would further that objective with a lesser

disproportionate impact. In NAACP v. The Medical Center, Inc., 657 F.2d 1327 (3rd Cir. 1981), the Third Circuit Court of Appeals disagreed with this allocation of responsibility and concluded that the burden of persuasion on all elements must ultimately be met by the plaintiff.

23. Evans, Implications for Health Care Policy, cited n. 6, supra. See also, Rostand, et al., Racial Differences in the Incidence of Treatment for End-Stage Renal Disease, 306 New England Journal of Medicine 1276 (1982).

24. U.S. Bureau of the Census, Statistical Abstracts of the United States: 1981 (102d Ed.) Washington, D.C., 1981. These are raw figures and thus are not controlled for income.

25. See, Doe v. New York University, 666 F.2d 761 (1981). This case involved selection of best possible candidates for medical school and a claim of handicap discrimination. It suggests that maximum likelihood of clinical success would be a legitimate programmatic goal under Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. Section 794 (as amended 1978). Since it would survive analysis under Section 504, it would also likely survive analysis under Title VI, because the antidiscrimination provisions of Section 504 were explicitly modeled after those of Title VI.

26. Among the objectives that have been accepted by the OCR in the health area are improving accessibility of services, improving quality of services, and realizing necessary fiscal savings. See Chavkin, cited n. 3, supra.

Of course, any transplant selection program can have objectives beyond selecting those most likely to benefit from treatment. For example, the hospital or government may have research objectives which limit the types of patients it selects. Under Title VI, these must be assessed for their legitimacy. If the courts or if OCR find them legitimate, then they may be utilized by recipients.

27. Bellock and Hazelkorn have noted that "satisfying, cohesive, and supportive relationships" facilitate the patient recovery process. Bellock, and Hazelkorn, Psychological Aspects of Cardiac Illness and Rehabilitation, 37 Social Casework 483 (1956), cited in Evans, Dimensions of Family Impact Pertinent to Heart Transplantation, Update No. 8, National Heart Transplantation Study, Battelle Human Affairs Research Centers, June 22, 1982.

28. While the process of elimination of potential heart transplant candidates may start well before the patient is ever assessed at a transplant facility, we use the term "screeners" here to indicate the professionals on the transplant facility's staff

who formally assess patients for treatment suitability. At Stanford University's transplant facility, this group consists of a cardiologist, a social worker, and a cardiac surgeon. See, Christopherson, Heart Transplants, The Hastings Center Report (February 1982), p. 20.

Of course, the population actually interviewed by the transplant program has already been considerably narrowed through socio-cultural and geographic factors, which can result in lack of access to physicians who actively refer patients to transplant programs, and informal screening by physicians. While discussion of these factors is beyond the scope of this paper, they are noted with reference to access to health care in Civil Rights Issues in Health Care Delivery, cited n. 5, supra. See p. 14, infra, for a discussion of discriminatory referral practices.

29. 45 CFR Section 80.3(b)(1)(v) "a recipient may not on grounds of race, color or national origin: (v) Treat an individual differently from others in determining whether he satisfies any admission, enrollment, quota, eligibility, membership or other requirement which individuals must meet in order to be provided any service, financial aid, or other benefit under this program. . . .

(1) (i) Deny an individual any service, financial aid, or other benefit provided under the program."

30. In its 1981 report, the Institute of Medicine reviewed data on racial differences in health care utilization and noted that they were consistent with the hypothesis that minority groups' use of health care is influenced by patterns of discrimination by physicians. Health Care in a Context of Civil Rights, p. 44. As they noted, despite reports of physician discrimination in the form of segregated waiting rooms or office hours, there currently are no data on the extent to which racial discrimination exists in actually accepting or referring patients for treatment. Id. However, the possibility remains that racial-ethnic minorities are not being referred to heart transplantation (or accepted) for reasons unrelated to health or income status.

Flaherty and Meagher, in a study of 66 black and 36 white male schizophrenic inpatients, found blacks more likely than whites to have been given medications on an "as needed" basis, less likely to have received recreation and occupational therapy, and more likely to have been put in seclusion and to have restraints used. Flaherty and Meagher, Measuring Racial Bias in Inpatient Treatment, 137 American Journal of Psychiatry 679 (June 1980). These differences appear to have been due to subtle racial stereotyping among staff members and their greater

familiarity with white parents, rather than to racial differences in pathology. Ibid. Similarly, in a study of racial differences in the treatment of children in five mental health clinics, Jackson, Berkowitz, and Farley found that black children were less likely than white children to be accepted for treatment, less likely to receive individual eligibility treatment, and (at two clinics) likely to be seen for a lesser length of time. Jackson, Berkowitz, and Farley, Race as a Variable Affecting the Treatment Involvement of Children, 13 Journal of the American Academy of Child Psychiatry 20 (1974).

31. Studies indicate that a variety of factors affect low minority utilization of all forms of health care. They include residential patterns, differences in socioeconomic status, ethnic differences in concepts and values associated with disease and treatment, constraints and incentives that are built into federal health programs, and, possibly, discrimination.

These same factors apply with special force to access to heart transplant programs, since we must first gain access to referral physicians, typically specialists, before being formally considered at all. In addition, lowered health status associated with poverty may eliminate many more minorities from active consideration as heart transplant recipients. For a review of the studies mentioned above, see Health Care in a Context of Civil Rights, cited n. 5, supra, Ch. 2.

32. 45 C.F.R. Section 80 et seq. (1979).

33. "Guidelines for the Compliance of Hospitals with Title VI of the Civil Rights Act of 1964," Revised and Issued by Leon Pannetta, Director, Office for Civil Rights, Department of Health, Education and Welfare, November 1969.

34. 45 C.F.R. Section 80.3(b)(v).

35. Id. at Section 80.13(g). The term "recipient" in the Title VI regulations does not refer to the heart transplant recipient. Rather, the term refers to the program receiving federal financial assistance.

36. Cited supra, n. 33.

37. Id.

38. 45 C.F.R. Section 80.13(h).

39. 42 U.S.C. Section 2000(d)4 (1976).

40. Letter to Louis Nunez, Staff Director, U.S. Commission on Civil Rights, from Patricia Roberts Harris, Secretary of HHS, June 9, 1980, p. 865.

Medicare Part A covers hospital insurance benefits for the aged. See, 42 U.S.C.A. Sections 426, 1395-1395b-1, 1395c-1395i, 1395x-1595rr (1974 and Supp. 1980).

Medicare Part B is a voluntary, supplementary health care plan that pays 80 percent of a patient's costs for various medical, health and home care services regardless of whether these services are provided in a hospital, clinic, office or home. 42 U.S.C.A. Sections 1395K, 1395-1, 1395m (1974 and Supp. 1980).

41. Letter from Patricia Roberts Harris to Louis Nunez, June 9, 1980, in Civil Rights Issues in Health Care Delivery, cited n. 5, supra. Medicaid and Medicare Part A are accordingly listed in the Department's Title VI regulations under Appendix A, which describes some of the federal financial assistance programs to which Title VI applies.

42. In the 1965 opinion of the HEW General Counsel (letter dated July 5, 1968, in Civil Rights Issues in Health Care Delivery, n. 5, supra), the rationale was advanced that payments under Medicare Part A constitute federal financial assistance within the meaning of Title VI because as "reimbursement(s) equal to cost they in fact redound to the financial benefit of providers of service as a class." HEW Internal Memorandum from Alanson W. Willcox, General Counsel to Robert M. Ball, Commissioner of Social Security, October 18, 1965, at 1 (hereafter HEW Memo I). Under such an analysis, it was stated, monies disbursed under Part B could not be described as federal financial assistance because they are limited to 80 percent of the reasonable costs. Id. at 3. In a 1966 opinion, the General Counsel reiterated the position taken the preceding year but repudiated the original supporting rationale. The 1966 memorandum concluded that payments under Part A are federal financial assistance because they "are designed to finance the program or activity of a non-Federal institution or agency . . . even if there were no element of financial benefit to the recipients." HEW Internal Memorandum from Alanson W. Willcox to Robert M. Ball, December 30, 1966, at 1 (hereafter, HEW Memo II). Because such an analysis does not distinguish programs that reimburse reasonable costs from programs that reimburse only 80 percent of reasonable costs, the rationale advanced in HEW Memo I for excluding Part B from Title VI coverage was no longer tenable. The General Counsel, nevertheless, concluded in a footnote with minimal analysis that Medicare Part B is excluded as a contract of insurance. HEW Memo II, supra, at n. 10.

43. This rationale is presented in both Memos I and II. HEW Memo I stated that "[i]t is clear that Title VI does not apply to programs in which payment is made by the Federal Government directly to the ultimate beneficiary, such as the Social Security cash benefit program, and it would appear that the same

principle is applicable to Part B of Title XVIII [Medicare]." Memo I at 3. However, because Part B provides for some payments directly to providers the Memo based its conclusion of exclusion not so much on this "direct payment" rationale as on the less than complete nature of the reimbursement. HEW Memo II, while premising exclusion of Part B from Title VI on the contract of insurance theory, also discussed the "direct payment" rationale. Memo II at 5, 8-9.

This rationale was rejected in Bob Jones University v. Johnson, 396 F.Supp. 597 (D.S. 1974), aff'd 529 F.2d 51 (5th Cir. 1975). Since federal cash payments made directly to veteran students upon enrollment at an approved school were held to constitute federal financial assistance to the university, it was therefore subject to Title VI. The district court stated that "the method of payment does not change the nature of the program or the basic rate of school participation in the program."

44. See, United States Commission on Civil Rights, IV. "The Federal Civil Rights Enforcement Effort--1974: To Extend Federal Financial Assistance," 118-119 (1975). and Memo to Louis Nunez, Staff Director U.S. Commission on Civil Rights from Eileen M. Stein, General Counsel, U.S. Commission on Civil Rights (Oct. 7, 1980) in Civil Rights Issues in Health Care Delivery, cited at n. 5, supra.

Eileen Stein, General Counsel of U.S. Commission on Civil Rights, concluded that:

> Supplemental Medical Insurance Benefits are clearly Federal financial assistance and are not excluded from Title VI as either contracts of insurance or by reason of the method of their payment. A determination of the applicability of Title VI to Medicare Part B requires only a straightforward programmatic analysis of the structure and legislative history of the statutory plan to determine who the intended beneficiaries and recipients are and what programs or activities are being assisted in what manner.
>
> The program and activities assisted under Medicare Part B are clearly those medical services for which payments will be made under the statute when provided to eligible individuals. Thus, it becomes apparent that the recipients of Federal funds under Part B are the health care providers and the beneficiaries are those for whom such care is provided. Whether participation in the program by recipients results in financial gain for them is irrelevant. Part B generally contemplates direct payments to beneficiaries but such payment is contingent upon their receipt of those health services

which the statute is designed to assist. Indeed, ascertaining the intended beneficiaries and the intended recipients under this program is assisted by the fact that provision is made for payment directly to providers. It thus appears that Medicare Part B is subject to Title VI, and the Department of Health and Human Services is mistaken in its present view. Ibid.

45. In Cook v. Ochsner Foundation Hospital, Docket No. 70-1969 (ED La, Memorandum and Order on Defendant's Motion to Dismiss, entered Jan. 30, 1981), at 9. The district court of New Orleans ruled orally that Medicare Part A was federal financial assistance. No ruling was made on Medicare Part B since the case involved compliance of hospitals, not individual physicians. We know of no case that has ruled on the applicability of Title VI to Medicare Part B.

46. In a short, cryptic paragraph the district court in McLeod v. College of Artesia, 312 F.Supp 498 (1970), said that it did not have jurisdiction where "out of a total of over 3 million dollars budgeted and spent by the college in its four-year existence, approximately $53,000 came from a governmental source. In addition, the court found it significant that there was no showing that the federal program under which the money had been received had been administered in a discriminatory fashion.

47. See Wing, cited n. 3, supra.

48. OCR relies primarily on seeking voluntary compliance from recipients who are found in violation of Title VI, although it can order withdrawal of federal financial assistance from the recipient. For the individual provider, the latter sanction would mean withdrawal of the right to be reimbursed for services provided under the Medicaid and, arguably, the Medicare programs. However, this may not be a very effective deterrent to one who is not heavily involved in treating those individuals and thus would not be significantly financially affected by the inability to treat Medicare or Medicaid patients.

49. Under this doctrine, a master is liable in certain cases for the wrongful acts of his or her servant, and a principal for those of his or her agent. The master or principal is generally responsible for want of care on the servant's or agent's part toward those to whom the master owes a duty to use such care, provided the servant's or agent's failure to use such care occurred in the course of employment. Shell Petroleum Corp. v. Magnolia Pipe Line Co., Tex. Civ. App. 85 S.W.2d 829, 832.

50. OCR Guidelines, cited n. 33, supra.

51. The regulations state that a recipient "may not take actions that are calculated to bring about indirectly what this regulation forbids it to accomplish directly." 45 C.F.R. Section 80.5(b).

52. OCR Guidelines, cited n. 33 supra.

53. Pub. L. No. 93-112, 87 Stat. 390 (1973).

54. Coleman v. Darden, 594 F.2d 533 (10th Cir.) cert. denied 444 U.S. 927 (1979). The Rehabilitation Act is modeled after Title VI.

55. The Act was amended by the Rehabilitation, Comprehensive Services, and Developmental Disabilities Act of 1978, Pub. L. No. 95-602, 92 Stat. 2955.

56. See cases cited n. 10, supra.

57. Federal agency action is also unaffected by the 1974 National Health Planning Resources Development Act, Pub. L. No. 88-352, which requires the planning agencies created under the act to consider civil rights factors in making decisions about matters such as the approval of new services.

58. "Memorandum of Understanding between the Office for Civil Rights (HHS) and the Health Care Financing Administration," July 27, 1979.

59. Id.

Section 3

1. Health Care Financing Administration. Medicare Program: Solicitation of Hospitals and Medical Centers to Participate in a Study of Heart Transplants, 46 Federal Register 7072-7074, January 22, 1981.

2. 46 Federal Register 7073, January 22, 1981. The distinction between age as a "strongly adverse factor" as used in the Federal Register notice and its use as an absolute exclusionary criteria is not clear. Functionally, an individual apparently could present evidence overcoming a strongly adverse factor, while an exclusionary criterion would be deemed conclusively presumptive of his or her ineligibility.

3. 42 U.S.C. Sections 6101-6107 (1976) as amended by Amendments to the Older Americans Act of 1965, Pub. L. No. 95-478, 92 Stat. 1555 (1978).

4. 42 U.S.C. Section 2000d.

5. 20 U.S.C. Sections 1681-1686 - prohibiting sex discrimination in federally assisted education programs.

6. 29 U.S.C. Section 794 - prohibiting discrimination on the basis of physical or mental handicap in federally assisted programs.

7. Implementation of the Act only began with the issuance of the then-Department of Health, Education and Welfare (HEW) general government-wide regulations on June 12, 1979 (45 C.F.R. Section 90). Regulations consistent with them were then issued by "each Federal department or agency which extends Federal financial assistance to any program activity by way of grant, entitlement, loan or contract other than a contract of insurance or guaranty." 42 U.S.C.A. Section 6103(a)(4).

8. Figures cited in Schuck, The Graying of Civil Rights Law: The Age Discrimination Act of 1975, 89 Yale Law Journal 27, 30 (1979).

9. Schuck, note 8, supra.

10. United States Commission on Civil Rights, I. The Age Discrimination Study (1977). Hereinafter referred to as the "Commission Report".

11. The Commission Report studied the Community Mental Health Center program, the Legal Services program, the Vocational Rehabilitation Basic Grants program, the Community Health Centers program, the Title XX Social Services program, the Comprehensive Employment and Training Act program, the Food Stamp program, the Medicaid program, the Vocation Education Basic Grants program, the Adult Basic Education program, and the admissions policies of higher educational institutions.

12. Commission Report, p. 2. This definition is referred to as tentative, but evidently was never revised by the Commission.

13. The "reasonableness" exceptions are described in detail below.

14. Commission Report, p. 44. The two suggested exceptions were for: (1) any action specifically directed or provided by the terms of a federal statute that provided age-conditioned benefits or established age-related criteria for participation, and (2) affirmative action. That age may be an important factor in federal funding of heart transplantations is amply illustrated by the history of patient selection with end-stage renal disease (ESRD). In 1972, Congress passed P.L. 92-603 extending Medicare benefits to virtually all ESRD patients. An analysis of the demographic characteristics of patients before and after the establishment of the federal funding program dramatically illustrates the changes which take place:

Age of Hemodialysis Patients

	1967 %		1978 %	
< 25		8.0		3.4
25-34	24.0		10.0	
35-44	32.0		14.6	
45-54	27.0		25.8	
≥ 55		7.0		45.7
unknown		2.0		0.5

From Evans, Blagg and Bryon. Implications for Health Care Policy: A Social and Demographic Profile of Hemodialysis Patients in the United States, 245 Journal of the American Medical Association 487, 488 (1981).

15. 44 Federal Register 33,768.

16. 45 C.F.R. Section 90.12, hereinafter referred to as the Rules.

17. 42 U.S.C. Section 6103(c).

18. 45 C.F.R. Section 90.49(b).

19. 45 C.F.R. Section 90.49(c).

20. 42 U.S.C. Section 1601. The State and Local Assistance Act of 1972 (31 U.S.C. Section 1221) refers to programs or activities funded under general revenue sharing. The prohibitions of the ADA and Section 504 of the Rehabilitation Act also apply to any program or activity of a state or local government unit that receives funds made available through general revenue sharing.

An important issue for present purposes is the applicability of the ADA to health care providers under the Medicare and Medicaid programs. By analogy to Title VI and Section 504, the ADA would be applicable to providers under Medicaid and under the basic (Part A) Medicare program. Part B of Medicare, which provides for supplementary medical insurance at the option of the beneficiary, generally has not been construed to constitute federal financial assistance under either Title VI or Section 504. 45 C.F.R. Section 84, app. A, subpart A.

21. One exclusion is for employment practices, broadly excluding the practices of any employer, employment agency, labor organization, or labor-management joint-apprenticeship program receiving funds under the Comprehensive Employment and Training Act. 42 U.S.C. Section 6103(c)(1). The other, discussed here, relates to programs "established under authority" of certain laws.

22. 42 U.S.C. Section 6103(b)(2).

23. For example, the definitions of crimes and the imposition of punishment can turn on the perpetrator's age, e.g., Ill. Rev. Stat. Chapter 38, Section 11(a); publicly supported schools exclude those too young, Hammond v. Marx, 406 F.Supp. 853 (D.Me. 1975), and have barred those supposedly too old, Purdie v. University of Utah, 584 P.2d 831 (1978); and zoning laws may exclude children from buildings and communities, see Dayle, Retirement Communities: The Nature and Enforcibility of Residential Segregation by Age, 76 Michigan Law Review 64 (1977).

24. Schuck, note 8, supra.

25. The conclusion is supported by two pieces of evidence: (1) Congress told HEW officials that the phrase "any law" was not meant to be limited to federal law, but should also include state and local law; and (2) an amendment containing the phrase "specifically directed or provided by the terms of a federal statute" was eliminated.

26. Schuck, note 8, supra, at p. 62.

27. Slip opinion, May 30, 1980.

28. Contrast this use of "reasonableness" as an underlying assumption with that implied in Title VI. Racial distinctions would not be acceptable under Title VI even if they were deemed "reasonable." As opposed to age distinctions, racial classifications must be "necessary" to vindicate a "substantial" government interest. Except those classifications favorable to certain minorities, no racial distinction has met the test in the last 35 years.

29. In the leading case of Massachusetts Board of Retirement v. Murgia, 427 U.S. 307 (1976), the Supreme Court noted that the aged did "not define a discrete and insular group . . . in need of extraordinary protection from the majoritarian political process."

30. See O'Donnell, Lasser & Bailor, The Federal Age Discrimination Statute: Basic Areas of Controversy, and Suggestions for Compliance, 15 Wake Forest Law Review 1 (1979).

31. 42 U.S.C. Section 6103(b)(1)(A).

32. 29 U.S.C. Section 623(f)(1).

33. 42 U.S.C. Section 2000e-2(e).

34. In Dothard v. Rawlinson, 433 U.S. 321 (1977), however, the Supreme Court noted that the BFOQ exception in Title VII was intended as an extremely narrow exception to the general prohibition against sex discrimination.

35. 29 U.S.C. Section 623(f), employment-related BFOQ; 42 U.S.C. Section 2000e-2(e), Title VII BFOQ.

36. For example, Marshall v. Westinghouse Electric Corporation, 576 F.2d 588 (5th Cir. 1978); Lindsey v. Southwestern Bell Telephone Company, 546 F.2d 1123 (5th Cir. 1977). None, however, have reached the Supreme Court.

37. 531 F.2d 224 (5th Cir. 1976).

38. 521 F.2d at 236.

39. 45 C.F.R. Section 90.

40. 44 Fed. Reg. 33, 774.

41. 42 U.S.C. Section 6103(b)(1)(A).

42. Schuck, note 8, supra.

43. 124 Cong. Rec. H11, 451 (daily ed. October 4, 1978).

44. 45 C.F.R. Section 90.14.

45. 42 U.S.C. Section 6103(b)(1).

46. 29 U.S.C. Section 623(f)(1). The Equal Pay Act, 29 U.S.C. Section 206(d)(1) similarly prohibits sex discrimination in wage levels "except where such payment is made pursuant to . . . (iv) a differential based on any factor other than sex."

47. Personnel Administrator of Massachusetts v. Feeney, 99 S. Ct. 2282 (1979), upholding a veteran's preference statute that overwhelmingly benefitted the class of males.

48. Note, however, that, in the absence of adequate justification, even facially neutral factors may violate a statute specifically designed to limit the use of such factors. See Washington v. Davis, 426 U.S. 229 (1976); Griggs v. Duke Power Company, 401 U.S. 424 (1971). Title VII does not preclude the use of employment testing or measuring procedures, but does prohibit their use unless they can be demonstrated to be reasonable measures of job performance. Similarly, regulations adopted under Title IX, 45 C.F.R. Section 86.21(b)(2) require that defendants validate facially neutral criteria that have disproportionately adverse impacts on the basis of sex.

49. 29 C.F.R. Sections 860.103-.104.

50. 45 C.F.R. Section 90.15.

51. 44 Fed. Reg. 33, 774.

52. 44 Fed. Reg. 33, 783.

53. 491 F.Supp. 290 (D. Del. 1980).

54. 491 F.Supp. at 317 (D. Del. 1980). Note, however, that in 1978 the Congress removed the word "unreasonable" from the ADA's statement of purpose. The Delaware Court in 1980 apparently chose to ignore this change in purpose.

55. See Schuck, note 8, supra; Alexander, Shucking Off the Rights of the Aged: Congressional Ambivalence and the Exceptions to the Age Discrimination Act of 1975, 57 Chicago-Kent Law Review 1009 (1981).

56. Thus age is commonly used as a measure of the likelihood of experiencing particular kinds of medical problems, as in medical programs that specialize in serving certain age groups. In addition, however, age is used to measure:

    1) intellectual, physical and/or emotional maturity in minimum age requirements for certain educational programs;

    2) readiness to assume adult responsibilities in minimum age requirements for voting, alcohol consumption, and possession of firearms;

    3) the likelihood of possession of certain risk factors as in concentrating breast cancer screening programs on women above a certain age;

    4) certain physical abilities as in separating sports leagues by age; and

    5) the expected duration of future employability or service as in concentrating job-training programs on younger aged workers.

Section 4

1. The United States Supreme Court in recent years appears to have delineated a basic constitutional right of decisional autonomy and has subsumed it under the misnomer of "right to privacy." One commentator noted that:

> It has been sufficiently noticed that what the court has been talking about is not at all what most people mean by privacy. . .(T)he court has been vindicating not a right to freedom from official intrusion, but to freedom from official regulation. . .That the court cites search and seizure cases as precedent for its new zone of autonomy suggests that it does not distinguish between privacy and autonomy and may be treating them both as aspects of the 'right to be let alone.' But they are, I think, different notions conceptually, with different philosophical, political and social (and one might have thought, legal) assumptions and consequences; they may look different also if viewed as aspects of the confrontation of private right with public good.. . . Henkin, Privacy and Autonomy, 74 Columbia Law Review 1424 (1974).

Regardless of the nature of the different 'rights' subsumed under the heading of "privacy," the commentators and courts have used this term at various times to include interests in: (a) decisionmaking autonomy generally; (b) decisionmaking autonomy with respect to certain matters in particular (procreation, sexual relations, dying, medical treatment), (c) bodily integrity (covering matters of abortion and intrusions into the body (medical or otherwise)); (d) controlling one's own mental processes (e.g., by avoiding or accepting treatment with mind-altering drugs; (e) determining generally what knowledge or information one acquires; (f) controlling dissemination or having access to information about oneself or one's family; (g) freedom from searches, observation or inspection of ones effects (e.g., remote electric monitoring of a person's activities. Thus, it is impossible to give a unitary meaning to the courts notion of privacy except to say that it encompasses many varying interests. Shapiro & Spece, Bioethics and Law, Case Materials and Problems, West 1981, p. 55.

We use the term "right of privacy" in this section to refer to "autonomy" aspects that have been labelled as privacy by the courts. A variety of constitutional rights that seem to involve aspects of autonomy have been grounded on theories of privacy--e.g., rights to contraception, abortion, procreation, shock treatment, rights against psychosurgery, behavior therapy and life prolonging treatment. Id. at p. 55.

While even this decisional 'autonomy' aspect of the right to privacy has different variations, it is, as Henkin states, primarily and principally:

> . . .a zone of prima facie autonomy, of presumptive immunity from regulation, in addition to that established by the First Amendment. The zone, Justice Blackman told us, consists of 'personal rights' that can

> be deemed fundamental, that are implicit in the concept of ordered liberty.' But we will know which rights are and which are not within the zone only case by case, with lines drawn and redrawn, in response to individual and societal initiatives and the imaginativeness of lawyers. Henkin, Privacy and Autonomy, 74 Columbia Law Review 1424-26 (1974).

2. Henkin, Privacy and Autonomy, 74 Columbia Law Review 1410, 1412-14 (1974).

3. The term "right" has undertaken several different meanings in constitutional law and philosophy. Hare has pointed out the variations:

> . . . A has a right, in one sense of the word, to do X if and only if it is not wrong for A to do X, . . . A has a right, in another sense to do X if and only if it is wrong to prevent A from doing X; . . . A has a right, in another sense, to do X if and only if it is wrong not to assist A to do X (the extent of the assistance, and the persons from whom it is due, being unspecified, and on many occasions of the use of this "ambiguous word 'rights,' unspecifiable)." Hare, Abortion and the Golden Rule, 4 Philosophy and Public Affairs 201, 203 (1975).

An example of the first sort of right is the right of any of several drowning persons to seize a plank, to the exclusion of others. The competitors arguably have no duty not to interfere with each other. The second sense of "right," non-interference, is probably the most common usage in western political and moral theory. The third sense, which is called by some a 'welfare right,' has few indications in current constitutional law. The principle examples are the assistance of indigent persons accused of crimes.

4. See, e.g., Roe v. Wade, 410 U.S. 113 (1973).

5. Until the mid-1930's, the Supreme Court scrutinized carefully and frequently struck down regulations and laws affecting economic and property rights on the basis of a fundamental values analysis. Regulation of prices, labor relations, and conditions for entry into business were especially vulnerable. The most famous example of the substantive due process approach is Lochner v. New York, 198 U.S. 45 (1905), in which the Supreme Court struck down a law regulating the maximum working hours of bakers. On substantive due process, see generally, Gunther, G., Cases and Materials on Constitutional Law, 10th ed., Foundation Press (1979), Ch. 9, pp. 502-544. For a case that represented the substantive due process protection of economic and property rights, see West Coast Hotel Co. v. Parrish, 300 U.S. 379 (1937).

6. The state may "(reach) a conclusion and (act) on it legislatively . . . (even if) there is no conclusive evidence or empirical data. Paris Adult Theatre I v. Slaton, 413 U.S. 49, 63 (1973). The wisdom, need, or appropriateness of the legislation will not be reviewed by the courts, Whalen v. Roe, 429 U.S. 589, 597, n. 19 (1979). "It is enough that there is an evil at hand for correction and that it might be thought that the particular legislative measure was a rational way to correct it." Williamson v. Lee Optical, Inc., 348 U.S. 483, 488 (1955).

7. See Bice, Standards of Judicial Review under the Equal Protection and Due Process Clauses, 50 Southern California Law Review 689, 709-10 (1977); and Spece, R., A Purposive Analysis of Constitutional Standards of Judicial Review and a Practical Assessment of the Constitutionality of Regulatory Recombinant DNA Research, 51 Southern California Law Review 1281 (1978).

8. Moreover, because the state is generally free to distribute burdens and benefits as it deems appropriate (absent an impermissible purpose), it would be free to prefer one group over another for receipt of government health care benefits.

9. 410 U.S. 113 (1973).

10. 381 U.S. 479 (1965).

11. 405 U.S. 438 (1972).

12. Roe v. Wade, 410 U.S. 113 (1973), and Doe v. Bolton, 410 U.S. 179 (1973), appear to rest in part on a recognition of a privacy or liberty interest for the physician in treating willing patients. However, the Court has indicated in a subsequent case that the physicians' right is derivative of the patients' fundamental right. Whalen v. Roe, 429 U.S. 589, 604 (1977). It is therefore unlikely that any restrictions on the availability of a particular procedure would be invalidated solely on the ground that they restricted the physician's right to freely practice medicine.

13. 381 U.S. 479 (1965).

14. 381 U.S. at 484 (1965).

15. 405 U.S. 438 (1972).

16. Baird was purportedly decided on equal protection-minimum rationality grounds, although in fact the scrutiny applied seemed more stringent. The Court held that the statute violated the rights of single persons under the equal protection clause. It reasoned that ". . . (i)f under Griswold, the distribution of contraceptives to married persons cannot be prohibited, a ban on

distribution of contraceptives to unmarried persons would be equally impermissible." 405 U.S. at 453. Despite the grounding of the opinion on the equal protection clause, the Court made some significant comments on the Griswold privacy right:

> It is true that in Griswold the right of privacy in question inhered in the marital relationship. Yet the marital couple is not an independent entity with a mind and heart of its own, but an association of two individuals, each with a separate intellectual and emotional make up. If the right of privacy means anything, it is the right of the individual, married or single, to be free from unwarranted governmental intrusion in matters so fundamentally affecting a person as the decision whether to bear or beget a child. Id.

17. 410 U.S. 113 (1973).

18. 410 U.S. at 153 (1973).

19. The Court mentioned specific detrimental effects on the pregnant woman, such as harm to her health in early pregnancy, the distressful life of maternity, psychological harm, taxation on the mother's physical health caused by caring for a child, and the possible distress in raising an unwanted child in a home psychologically unable to care for it. 410 U.S. at 153.

20. The Court found that the state has important interests in the protection of the public's health: "(A) state may properly assert important interests in safeguarding health, in maintaining medical standards, and in protecting potential life." 410 U.S. at 154.

21. Id.

22. 429 U.S. 589 (1977). Whalen involved a New York statute that required extensive record-keeping of the names of lawful users of certain narcotic drugs. The individuals challenging the law invoked both aspects of the right of privacy (i.e., avoiding disclosure of personal matters, and independence in decision-making), but the Court held that the risks of unauthorized disclosure of confidential information did not outweigh the state's interest in regulating dangerous drugs, emphasizing that the law contained careful security provisions. The Court also rejected the claim of impingement on the interest in making certain decisions independently. It apparently found that there was not a sufficient impingement on the right to warrant applying a heightened level of scrutiny; the crucial factor was that ". . . no individual has been deprived of the

right to decide independently, with the advice of his physician, to acquire and use needed medication." 429 U.S. at 603.

Yet the recognition of the decisional right itself is less than clear. In one segment of the opinion, the Court cast some doubt on whether regulations that restricted the availability of certain drugs would be subject to strict scrutiny at all. It stated that ". . . although the state no doubt could prohibit entirely the use of particular schedule II (i.e., narcotic) drugs, it has not done so. This case is therefore unlike those in which the Court has held that a total prohibition of certain conduct is an impermissible deprivation of liberty. Id. The court footnoted this statement with ". . . it is, of course, well settled that the state has broad powers in regulating the administration of drugs by the health professions." Id., n. 19.

The latter statement may be interpreted to mean that something less than strict scrutiny will be applied to state regulation of pharmaceuticals, even though such regulation may impinge upon the ability of the individual to seek out a preferred method of treatment. Alternatively, such statements support the view of one commentator who suggests that, absent a showing of an "impingement," strict scrutiny will not be applied even where the court recognizes the existence of a fundamental right.

It is clear from the court's opinions that the proper scope of the privacy right remains unsettled. In a footnote to his Whalen opinion, Justice Stevens observed that in Paul v. Davis, 424 U.S. 693, 713 (1973), the Court had characterized the privacy decisions as dealing with "matters relating to marriage, procreation, contraception, family relationships, and child rearing and education." 429 U.S. at 603. While the footnote is in the form of an observation rather than a recognition of a limitation on the scope of the privacy right, its placement may indicate that at least some members of the Court are reluctant to further expand the areas covered by the privacy right.

By contrast, Justice Brennan's majority opinion in Carey v. Population Services Int'l., 431 U.S. 678 (1977), noted that the outer limits of the "interest in independence in making certain kinds of decisions" as recognized in Whalen, "have not been marked by the court." 431 U.S. at 684.

The dicta in Whalen concerning the broad regulatory powers of the state suggests that, at minimum, many forms of regulation will not constitute a sufficiently burdensome impingement on either aspect of the recognized privacy right to warrant heightened scrutiny. Under this interpretation, the state's power to regulate would not be circumscribed unless the person challenging the regulation could show that it either posed a significant impingement on the exercise of the privacy rights,

or could not meet the rationality requirement of the rational basis test. While unstated, the latter view seems to be more consistent with the Court's earlier statements regarding the existence of the fundamental privacy right.

23. Andrews v. Ballard, 498 F. Supp. 1038, 1048 (S.D. Tex. 1980). The Court appears to be treating the privacy/autonomy right more flexibly than other fundamental rights, even in the areas where it is recognized. As one observer has noted:

> Unlike most fundamental rights, the right of privacy has had to give way before the compelling state interest that seems so hard to find when other fundamental rights have been reviewed. . . . The pattern seems to be that the Court has left the rigid bounds of strict scrutiny or rational basis dichotomy and is now willing to look for compelling state interests as possibly counter-vailing any fundamental right of privacy it may have found.

Comment, Laetrile: Statutory and Constitutional Limitations on the Regulation of Ineffective Drugs, 127 University of Pennsylvania Law Review 233, 262 (1978).

Another commentator has suggested that the Court has altered fundamental rights analysis by increasingly emphasizing the need to show an actual "impingement" on a fundamental right before strict scrutiny will be applied. Any official restriction that falls short of impingement will be subject to the considerably less demanding rationality test. She noted that:

> Even before Maher, recitation of the criteria for strict scrutiny routinely included an impingement requirement. However, the Court often appeared equally ready to apply the test to less intrusive conjunctions of state action and individual fundamental right. Thus, the nature of the individual interest asserted apparently triggered strict scrutiny even if that interest was only "affected," "involved," "abutted," "touched upon," "implicated," or "at stake." "Impingement" served not as a discrete substantive requirement but rather as one synonym for the presence of any state action. Until at least the early 1970's, identifying those rights deemed fundamental preoccupied the Court, and it paid little heed to the character of the state action challenged in such cases. . . .

> . . . If the Court considered the character of the state action in these cases, it did so at a different point in the analysis. After determining that strict scrutiny applies to protect fundamental rights, the Court sometimes explained the burdensomeness of the action undertaken to further the government's asserted compelling interest. Then, . . . the Court would generally uphold slight burdens on the individual right but would strike down substantial ones, if alternative, less burdensome means were available. By contrast, Maher and McCrae dictate that the character of the state action challenged will determine whether strict scrutiny applies at all. Appleton, Beyond the Limits of Reproductive Choice: The Contributions of the Abortion-Funding Cases to Fundamental Rights Analysis and to the Welfare Rights Thesis, 81 Columbia Law Review 721, 746-47 (1981). (Hereinafter cited as "Appleton.")

This observation provides an accurate description of the analysis undertaken in the Whalen opinion, and may explain how the court can both recognize that a fundamental right may apply in a given area and yet refuse to apply a heightened level of scrutiny. In the Whalen case, for example, the Court seemed to recognize both prongs of the privacy right, but nonetheless refused to apply strict scrutiny. The lack of evidence of a sufficient impingement could explain this otherwise analogous outcome. See Whalen v. Roe, 429 U.S. at 603.

24. It appeared that the Supreme Court would address this question in Mills v. Rogers, 50 U.S.L.W. 4676 (1982). However, in accordance with its policy of avoiding the unnecessary decision of constitutional issues, the Court remanded the case to the Court of Appeals to decide if such a state constitutional right had been recognized by an intervening decision of the Massachussets Supreme Court. Id. at 4679.

25. Many of the early cases in this area involved the rights of Jehovah's Witnesses to refuse blood transfusions. See, Cantor, A Patient's Decisions to Decline Life-Saving Medical Treatment: Bodily Integrity Versus the Preservation of Life, 26 Rutgers Law Review 228, 230-36 (1973).

26. See, e.g., In re President and Directors of Georgetown College, Inc., 331 F.2d 1000 (D.C. Cir), cert. denied, 377 U.S. 978 (1964); Raleigh Fitkin-Paul Morgan Mem. Hosp. v. Anderson, 42 N.J. 421, 201 A.2d 537, cert. denied, 377 U.S. 985 (1964) (legitimate state interest in the protection of an unborn child carried by the subject).

27. Jacobson v. Massachussetts, 197 U.S. 11 (1905) (the state's interest in preventing epidemics held to override the individual's right to refuse vaccination).

28. For example, one court held that an adult patient has the right to refuse blood transfusions despite medical opinion that "the patient's decision not to accept blood . . . was just about the taking of the patient's own life." Erickson v. Dilgard, 44 Misc.2d 27, 28, 252 N.Y.2d 705, 706 (1962) (special term).

In In re Maida Yetter, 62 Pa. D.C.2d 619 (1973), for example, the Court concluded that a patient could refuse to undergo surgery, noting that "the right of privacy includes a right to die with which the state should not interfere where there are no minor or unborn children and no clear and present danger to public health, welfare or morals." Id. at 623.

29. 70 N.J. 10, 355 A.2d 647 (1976).

30. 70 N.J. at 40. See also In re Colyer 99 W.2d 114 (1983).

31. In each case, the patient is asserting the right to make important treatment decisions free from unwarranted state intervention. While the nature of the state's interests in regulating unsafe or unproven medical treatments are probably different, the nature of the underlying right to decide arguably should not be affected by the efficacy of the treatment. Where the constitutional challenge involves procedures or treatments of an unorthodox nature, however, courts may be unwilling and thus may refuse to recognize the decisional right at all and may limit the ability of the state to regulate. The courts may be more receptive to constitutional arguments where the legal challenges involve therapies recognized as safe and efficacious by highly respected members of the medical community. Such cases have not yet arisen. One exception has been regulation of the availability of therapeutic abortion, which is often opposed for reasons other than its efficacy as a medical procedure. Another exception has been regulation of acupuncture, a treatment that is slowly gaining acceptance among segments of the American medical community (discussed below).

32. Rutherford v. United States, 438 F. Supp. 1287, 1296-1300 (W.D. Okla.), aff'd, 582 F.2d 1234 (10th Cir. 1977), rev'd, 442 U.S. 544 (1979). This case was the subject of nine orders and one administrative hearing by the Food and Drug Administration (FDA). The remarkable judicial history of the Rutherford litigation is as follows: Rutherford v. United States, 399 F. Supp. 1208 (W.D. Okla. 1975) (remanding to FDA), aff'd, 542 F.2d 1137 (10th Cir. 1976) (affirming the district court's remand to FDA), on remand, 424 F. Supp. 105 (W.D. Okla. 1977) (remanding to FDA), 429 F. Supp. 506 (W.D. Okla 1977) (again remanding to FDA and enjoining the FDA from preventing the importation and use of laetrile by the plaintiffs), 438 F. Supp. 1287 (W.D. Okla. 1977) (again remanding to FDA and enjoining FDA from preventing the importation of laetrile and its use by plaintiffs), aff'd, 582 F.2d 1234 (10th Cir. 1978) (affirming the district court's remand to, and injunction of, the FDA),

rev'd, 442 U.S. 544 (1979) (reversing and remanding to court of appeals), on remand, 616 F.2d 455 (10th Cir. 1980) (remanding to the district court to reverse the injunction), cert. denied, 101 S.Ct. 336 (1980).

33. 399 F. Supp at 1215. The trial court order allowed the importation of Mexican laetrile in sufficient quantity to treat the plaintiff for six months. 399 F. Supp. at 1212. The court concluded that the cancer victim should not be subject to criminal penalties for violation of 21 U.S.C. Section 355 for the possession and use of laetrile. The decision of the court seems to be based on the belief that the right of privacy includes the choice of treatment decision.

34. 542 F.2d 1137, 1144 (10th Cir. 1976).

35. While allowing the injunction to stand, the Tenth Circuit Court instructed the district court to remand the case to the FDA in order to determine whether laetrile was a "new drug" under the Federal Food, Drug and Cosmetic Act. 542 F.2d 1137 (10th Cir. 1976), rev'd, 442 U.S. 544 (1979). The significance of the status as a "new drug" lies in the fact that drugs which are not so classified can be "grandfathered" in, and would therefore be exempt from the efficacy requirements that apply to new drug applications. Only the drug's safety would then be within the jurisdiction of the FDA.

Judge Brennan directed the FDA to conduct administrative hearings to establish a record for their conclusion that laetrile was a new drug. 424 F. Supp. 105 (W.D. Okla. 1977).

Following FDA hearings, the FDA commissioner issued a decision in July, 1977, reported in 42 Fed. Reg. 39,768 (1977). He found that there was no uniform definition of laetrile, and that in its various forms, laetrile was a "new drug" under the Act because it was not generally recognized as safe and effective for use, and that the drug did not qualify for exemptions under either of the statute's grandfather clauses. Id. at 39,806. Rutherford challenged the findings of the report on statutory and constitutional grounds, arguing that laetrile was not a new drug, and that in any event, the FDA enforcement procedures against the interstate shipment of laetrile violated his constitutional rights. The district court sustained the Commissioner's findings that laetrile was a new drug. 438 F. Supp. 1287, 1292-93, (W.D. Okla.) aff'd, 582 F.2d 1234 (10th Cir. 1977), rev'd, 442 U.S. 544 (1979). While sustaining one of the grandfather clause denials, the court refused to sustain the other, because it depended on a showing that laetrile was unsafe at the time the clause was adopted, a finding that the court held was arbitrary and capricious and therefore an abuse of discretion. Id. The court therefore ruled that laetrile was

exempt from the premarket testing requirements. Id. at 1301. The court also held, for the first time in the case, that enforcement of the FDA ban on laetrile would constitute a violation of Rutherford's right of privacy:

> (By) denying the right to use a non-toxic substance in connection with one's own personal health care, FDA has offended the Constitutional right of privacy. Id.

(In the first district court opinion, the right of privacy was discussed without being invoked.) See, 399 F. Supp. 1208, 1214 (W.D. Okla. 1975), aff'd, 542 F.2d 1137 (10th Cir. 1976), rev'd, 442 U.S. 544 (1979).

36. 582 F.2d 1234 (10th Cir. 1978), rev'd, 442 U.S. 544 (1979).

37. Id. at 1235-36. (emphasis added).

38. Id. at 1236.

39. The court continued the permanent injunction that had been granted by the district court, by limiting it to permit only procurement of intravenous injections to be administered by a licensed medical practitioner to persons who were certified, by a licensed medical practitioner, to be terminally ill from some form of cancer.

40. 442 U.S. 544 (1979).

41. Id. at 555.

42. "For the terminally ill, as for anyone else, a drug is unsafe if its potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit." Id. at 555-56.

43. Id. at 556.

44. Id. at 559 n. 18. see n.35 for description of how the 'grandfathering' causes operate.

45. Id.

46. 616 F.2d 455 (10th Cir. 1980).

47. 616 F.2d at 457.

48. 101 S.Ct. 336 (1980).

49. Judkins v. United States, Food Drug Cos. L. Rep. CCH 38,179 (Dore 1978).

50. Id. at 38,730. Other cases have arisen concerning minors undergoing or seeking to undergo laetrile therapy which did not involve privacy arguments. Compare Custody of a Minor, ___ Mass ___ 393 N.E.2d 836 (1979) (affirming the denials of parent's request for laetrile treatment of their leukemic child) with in re Hofbauer, 47 N.Y.2d 648, 393 N.E.2d 1009, 419 N.Y.S.2d 936, 1979 (reaching opposite conclusion on a similar petition of parents of a child with Hodgkin's disease).

51. 498 F. Supp 1038 (S.D. Tex. 1980).

52. Id. at 1056-57.

53. Tex. Rev. Civ. Stat. Ann., arts. 4510, 4510b, 4505(12), (15), (Vernon 1976).

54. 22 T.A.C. Section 183.1-2 (1979).

55. See text at ns. 31-50, infra.

56. 498 F. Supp. at 1039.

57. Id.

58. See, e.g., Whalen v. Roe, 429 U.S. 589 (1977); Roe v. Wade, 410 U.S. 113 (1973); Eisenstadt v. Baird, 405 U.S. 438 (1972); Griswold v. Connecticut, 381 U.S. 479 (1965).

59. 498 F. Supp., at 1048.

60. 498 F. Supp., at 1047.

61. As noted earlier, the characterization of an interest as "fundamental" means that the statute is no longer presumptively valid. Rather than the plaintiff having to prove that the statute is unconstitutional, the state is forced to prove that it is necessary to promote a compelling state interest and is sufficiently narrowly drawn. Judge McDonald's characterization of the plaintiff's interest in treatment choice as fundamental therefore shifted the burden to the state to establish the constitutionality of its statute and regulations. This was undoubtedly the most important step in the decision to void the Texas Medical Practice Act.

62. Id. at 1052.

63. Id. at 1055.

64. 23 Cal.3d 697, 591 P.2d 919, 153 Cal. Rptr. 431, cert. denied, 444 U.S. 949 (1979).

65. The defendants argued the patient's right to laetrile derivatively. Id. at 713, 591 P.2d at 928, 153 Cal. Rptr. at 440.

66. 141 Cal. Rptr. 764, 777 (Dist. Ct. App. 1977).

67. Id. at 783-784.

68. Chief Justice Bird dissented on the ground that the right of privacy, under both the federal and state constitutions, "prevents the state from interfering with a person's choice of treatment on the sole grounds that the person has chosen a treatment that the state considers ineffective." 23 Cal.3d 697, 711-40, 591 P.2d 919, 927-46, 153 Cal. Rptr. 431, 439-58, (Bird, C.J., dissenting), cert. denied, 444 U.S. 949 (1979).

69. Id.

70. 591 P.2d 919, 922, citing Whalen v. Roe, 429 U.S. at 600, n. 26, which quotes Paul v. Davis, 424 U.S. 693 (1973). However, the Supreme Court has also observed, in a case decided after Paul and Whalen, that "(T)he outer limits of (the privacy interest in making certain kinds of important decisions independently) have not been marked by the Court. . . ." Carey v. Population Services International, 431 U.S. 678, 684 (1977).

Despite its clear holding that the right of privacy does not encompass the decision to obtain treatment, the analysis contained in the Privitera decision is muddled. In spite of its holding, the Court nevertheless felt constrained to point out that the Roe v. Wade privacy right in the abortion decision was not absolute. It is unclear why this should be of any significance after the Court's refusal to recognize a similar right to choose to undergo medical treatment; even though not absolute, the Roe privacy right still includes the decision whether or not to terminate a pregnancy. The court's misunderstanding of the analytical framework for fundamental rights cases is further illustrated by its statement, "Significantly, when danger to health exists, Roe v. Wade indicates that state regulation shall be tested under the rational basis standard." Id. In Roe v. Wade, however, the U.S. Supreme Court properly continued its high level of scrutiny throughout all stages of pregnancy, even those in which the state asserted an interest in protecting the health of the mother. The level of scrutiny did not shift from strict to rational basis upon the introduction of the health factor; rather, the Court held that, as the pregnancy progresses and the health hazards of abortion grow, a point is reached at which the privacy interests of the woman are outweighed by the state's interest in protecting her health. Even when the scale tips in favor of the state, however, the interests of the individual are

significantly more immune from governmental interference than would be the case if the rational basis standard were applied; even those legislative enactments justified by state assertion of a compelling interest must be "narrowly drawn to express only the legitimate interests at stake." Roe v. Wade, 410 U.S. 113, 156 (1973). No such requirement exists under the rational basis approach.

The California court then cited another Supreme Court abortion case, Planned Parenthood of Central Missouri v. Danforth, 428 U.S. 52 (1976). Danforth involved, among other things, a challenge to statutory provisions prohibiting the use of saline amniocentesis as a method of abortion after the first twelve weeks of pregnancy, on the ground that it operated to preclude virtually all abortions after the first trimester. The California Supreme Court interpreted Danforth to mean that while the abortion decision is within the zone of privacy and deserving of the compelling interest standard, the "selection of a particular procedure is a medical matter to which the privacy status does not attach." While part of the opinion of the Court was phrased in terms of the "reasonableness" of the legislation, the Court refused to uphold the saline ban, calling it an "unreasonable or arbitrary regulation designed to inhibit, and having the effect of inhibiting, the vast majority of abortions after the first twelve weeks." While striking the provision, this language was joined in by only four of the justices. Moreover, as Justice White pointed out in dissent, Missouri's scheme ought to have been upheld if it were simply measured under the rational basis test. 428 U.S. 52, 96-97 (White, J., concurring in part and dissenting in part). A majority of the Court, six months later in Carey v. Population Services International, explicitly held that where the state regulates rather than prohibits, in an area where a decision as fundamental as whether to bear or beget a child is involved, the proper standard is still the strict scrutiny standard, and thus regulations imposing a burden on the right must serve a compelling state interest and be narrowly drawn to express only the legitimate state interests at stake. 431 U.S. at 686.

The Court also relied on Whalen v. Roe, 429 U.S. 589 (1977). The gist of the Whalen holding, however, seemed to be that the effect of the regulation on treatment decisions was so small that it simply did not "constitute an invasion of any right or liberty protected by the Fourteenth Amendment." Id. at 603-04. Whalen seems to establish only that when no fundamental right is infringed and a danger to the health exists, state regulation shall be tested under the rational basis standard. However, contrary to the assertion by the Privitera court, when a fundamental right is infringed, state regulation shall be tested under the strict scrutiny test whether or not a danger to health exists. The Privitera majority cited as support for its position dicta in Whalen that "the state, no doubt, could

prohibit entirely the use of particular (narcotic) drugs." It reasoned that if the state has the power to ban a drug with recognized medical use because of its potential for abuse, then a state clearly has the power to ban a drug not recognized as effective for its intended use. 591 P.2d at 603. Yet if the state has the power to ban certain narcotic drugs, as the Court asserted in Whalen, it may be because such a ban is the most narrowly drawn means of achieving the compelling state interest in protecting the health and safety of the public; the fact that the state may prohibit some conduct entirely or regulate it heavily does not mean that the individual does not have a fundamental right to engage in that behavior. Even individual interests that are fundamental must be balanced against competing societal interests; thus, even though one has a fundamental right to choose abortion, it can still be prohibited during the third month of pregnancy when no alternative, less drastic means of protecting the health of the woman and the potential life of the fetus exist.

71. 155 N.J. Super. 593 (1977).

72. Rogers v. State Board of Medical Examiners, 371 So.2d 1037, Ct. App. cert. den., 376 So.2d 24 (Fla. 1979).

73. Id. at 1040.

74. 453 F. Supp. 1141 (M.D. Ala. 1978).

75. Id. at 1150.

CHAPTER 33

LEGAL ISSUES SURROUNDING THE DONOR

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Section 1 - THE SOURCE AND SUPPLY OF TRANSPLANTABLE HEARTS

A. INTRODUCTION

The increasing success of clinical heart transplantation at a limited number of transplant centers around the United States and the rest of the world enhances the potential for using transplantation as a routine medical treatment. Continued progress, however, is limited by two constraining factors--(1) a lack of effective immunosuppressive regimes to overcome rejection of the transplanted heart, and (2) the scarcity of donor hearts for transplantation. This section focuses on the latter element,[1] and examines the legal issues that arise regarding the source and supply of donor hearts.

The first section briefly discusses the question of the effect of Medicare reimbursement on donor organ availability and procurement. It also addresses the more general issue of organ shortage and resource allocation. Much of the material in this section is drawn from the experience of the End-Stage Renal Disease (ESRD) program, which provides a clear picture of the effect of full reimbursement on the demand for medical resources and donor organs. The second section discusses the legal implications and consequences of alternative methods of regulating the source and supply of donor organs. Although the focus of the section is on the role of the Uniform Anatomical Gift Act (UAGA), we also briefly consider the use of unclaimed body statutes and autopsy laws, compulsory removal proposals, and procedures for the sale of organs.

B. SCARCITY AND FUNDING: THE EFFECT OF MEDICARE REIMBURSEMENT

The general issue is the effect that Medicare reimbursement will have on the need[2] and demand for donor hearts for transplantation. In addition to common sense, there are two important lines of evidence that suggest that need and demand will increase dramatically under a reimbursement system.

1. THE NEED FOR DONOR ORGANS

Under current medical procedures,[3] approximately 100 individuals annually (103 in 1982) undergo heart transplantation in the United States. Even under these conditions, some patients die prior to transplantation because of the scarcity of suitable donor hearts. There are frequent appeals, both private and public, in the media for donor organs from patients whose lives hang in the balance.[4]

The potential explosiveness of the problem of organ demand is illustrated by the numerous efforts that have been made to estimate the need for replacement hearts. In 1969, the National Heart Institute[5] estimated that the number of potential candidates for heart replacement could range between 12,000 and 32,000 per year.[6] In 1972, the National Heart and Lung Institute[7] estimated that the potential number of candidates for clinically acceptable artificial hearts would range between 16,750 and 50,300 per year. Later,[8] it was suggested that 75,000 potential recipients for heart transplantation could be identified each year.[9] A more recent estimate is that approximately 1,000 transplant candidates realistically could be identified.[10] For our purposes, the

disparity among the estimates is not as important as their magnitude of all of them. The critical point is that even the most conservative estimate of the number of transplant candidates exceeds the current supply of available donor hearts by factors of ten.

2. THE EFFECT OF REIMBURSEMENT

As we noted above, even in the absence of a systematic reimbursement process, the demand for suitable donor hearts often exceeds the available supply. And a reimbursement program could be expected to seriously exacerbate this gap. The most widely studied analogy from which lessons can be learned is the experience of the End-Stage Renal Disease program. Data from that program dramatically illustrate the impact of reimbursement on demand for a medical resource. In 1965, there were approximately 300 individuals in the United States receiving long-term hemodialysis for kidney-related diseases. The number increased to 800, and to more than 1,000 by 1969.[11] In 1972, Congress amended the Social Security Act[12] to extend Medicare coverage to all ESRD patients.[13]

The Medicare legislation had a dramatic impact on the number of individuals receiving treatment under the ESRD program. By 1974, there were 10,300 patients receiving dialysis, and by 1976 that number had more than doubled to 24,500.[14] By 1980, the number had doubled again to more than 50,000.[15] The latest estimates are that the total number of persons covered under the ESRD program (including both transplants and dialysis) will reach 73,000 in 1982 and 87,000 by 1986.[16]

The numbers of patients under the ESRD program are not as

important as the pattern of change before and after the extension of Medicare coverage. Based on even the most crude estimates both of need and demand, it is fair to conclude that reimbursement, in the absence of some form of utilization control, signals (if not causes) a dramatic increase in demand for medical resources. The same patterns may hold for unrestrained reimbursement of heart transplantation--unfettered demand will overwhelm the supply of donor hearts available under the current system of organ retrieval.[17]

3. ORGAN SHORTAGE AND RESOURCE ALLOCATION

As Evans[18] notes, it is inevitable that health care resources will have to be allocated:[19]

> The U.S. population is aging; chronic disease is becoming more prevalent, disability a common occurrence. To meet the needs of an aging, chronically ill, and disabled population, a complex array of expensive and sophisticated medical technologies has emerged. The cost of these technologies will make it necessary to develop elaborate plans to not only enable them to be used, but to insure that people receiving them derive the maximum expected benefits. Thus, it is apparent that resource allocation decisions are likely not only to become a necessity, but to become routine.

In fact, such decisions are already made every day; physicians make decisions about who will be treated, hospitals restrict access to their facilities and resources, and insurance companies limit reimbursement for various medical services or procedures.[20] They are not, however, made with any degree of specificity, may not be the result of conscious deliberation, and are certainly not made in accordance with any generally agreed upon criteria. Such distribution is accomplished by limiting the availability of resources

(availability) or limiting individuals' access to those resources (accessibility). Both concepts are important in understanding resource allocation and the source and supply of organs for transplantation.

Two terms have been ascribed to these concepts, and the level at which they occur. "Rationing" is generally taken to refer to decisions made at the individual level--the decision to give a donor heart to person A rather than person B or C is a rationing decision. On the other hand, "allocation" refers to processes that occur at the aggregate or programmatic level--the decision to funnel resources to a transplant program rather than to preventive education is an allocation decision.[21] As we will discuss below, allocation and rationing are important in the consideration of alternative methods to ensure the source and supply of organs for donation. Some alternatives are directed at increasing the availability of organs, others at increasing individual accessibility to donor organs. The legal implications of each may also depend upon its characterization under this scheme.

C. ALTERNATIVE SOURCES: LEGAL CONSIDERATIONS AND CONSTRAINTS

Organs for transplantation can be retrieved from living or dead individuals. In the case of living persons, the principal legal issue is that of obtaining appropriate, informed consent.[22] Although consent may be problematic in the case of minor or incompetent donors,[23] there is little doubt that a competent adult can validly donate a non-vital organ.

However, when there is a need for an organ after the potential donor's death, the issue of consent and the validity of the person's donative intent are not clear. A number of competing interests stand in the way of routine utilization or salvage of organs. For example, before an organ can be taken, a balance must be struck between the presumed (and often explicit) wishes of the dead person and the spouse, or other next-of-kin; the medical and scientific need for cadavers, organs, and tissue; and the judicial need to determine cause of death through autopsy. In times past (and to a large extent today), there was no systematic legal scheme to regulate the disposition and utilization of dead bodies, or to harvest salvageable organs. Only in recent decades has it become possible to make a post-mortem donation of a body part with any assurance that the donation would be effectuated.[24]

As background to the discussion of alternatives for organ procurement, it is important to understand the origins of the legal doctrines surrounding dead bodies. This is critical to appreciating both the existing legal scheme and the legal and societal reluctance to implement other alternatives.

1. THE ORIGINS OF LEGAL CONTROL OVER DISPOSITION

Scholars agree that the disposition of dead bodies has historically been significantly shaped both by superstition and religion. Well into the 19th century, the disposition of dead bodies under English law was strictly within the province of the church.[25] Only in the latter part of the 17th century did the common law courts began to reassert jurisdiction over traditionally ecclesiastical

matters, but even then they continued to hold that no civil action could be maintained against someone who appropriated, mutilated, or defaced a corpse.

Lord Coke is frequently quoted for the proposition that "no one living person has a property right in a corpse." Coke noted that:[26]

> It is to be observed, that in every sepulcher, that hath a monument, two things are to be considered, viz. the monument, and the sepulcher or buriall of the dead. The buriall of the cadaver (that is caro data vermibus ("flesh given to worms")) is nullis in bonis ("among the property of no person"), and belongs to ecclesiastical cognizance, but as to the monument, action is given . . . at the common law for defacing thereof.

Thus, even after the decline of the ecclesiastical courts, the common law courts held to the principle that there were no property rights in a dead body.[27]

Because ecclesiastical law was not part of the common law tradition inherited by the United States, American judges never felt bound by ecclesiastical precedents. In addition, because of the multiplicity of religious practices (and atheistic or agnostic beliefs) common in the United States, there were far more choices regarding burial practices than were considered in ecclesiastical decisions. Early American law regulated the disposal of bodies only to the degree necessary to ensure decency and sanitation. The morass of law and speculation was finally clarified in 1856 with the publication of the Beekman Street report,[28] which outlined the American legal position with respect to the disposal of dead bodies. The Report stated that:[29]

(1) neither a corpse, nor its burial, is legally subject, in any way, to ecclesiastical cognizance, nor to sacerdotal power of any kind.

(2) the right to bury a corpse and to preserve its remains, is a legal right, which the courts of law will recognize and protect.

(3) such a right, in the absence of any testamentary disposition, belongs exclusively to the next-of-kin.

(4) the right to protect the remains includes the right to preserve them by separate burial, to select the place of sepulcher, and to change it at pleasure.

(5) if the place of burial be taken for public use, the next-of-kin may claim to be indemnified for the expense of removing and suitably reinterring their remains.

The law and the courts were never clear as to the nature of the "right" to bury a dead body. Some courts held the right to be one based on family relations, i.e., the right was based on the interest that a close relative had in the handling and treatment of the body of a dead relative;[30] and others have held that burial was simply a property right.[31] The most common view, however, was that the next-of-kin held a "quasi-property" right in the body for limited purposes.[32] The holder of the right was not the "owner" of the body, rather he or she held the body in trust for those who, through family relationships or friendship, may have an interest in its burial.[33]

In order to ensure that next-of-kin could exercise their right (and adequately discharge their obligation) to bury a body, the courts uniformly held that they had a right to receive the body in the

same condition as it was at the time of death. Thus, if the body was mutilated, or a part removed without their permission, the next-of-kin could recover damages. Consequently, the removal of tissue and organs for medical purposes could only be undertaken with the consent of next-of-kin. Many, if not most, such requests were denied, with objections based on emotional and aesthetic grounds, and out of respect for the body of the dead person.[34]

The development of a legal "right" in the next-of-kin to properly dispose of a dead body led to the unusual corollary that a living individual could not, through a will, direct the manner of his or her own burial because the body was not property and could not be included in the estate. Some courts later recognized the limited right of an individual to control the post-mortem disposition of his or her body, but limited that right to determinations of the place and manner (i.e., burial or cremation) of burial and authority for autopsy.

It was not until the 1960's that the American legal system directly recognized the right of an individual to direct the disposition of his or her body for use in medicine.[35] The most important case dealing with this issue is Holland v. Metalious,[36] where the will of Grace Metalious, the author of Peyton Place, provided for the donation of her body to either of two medical schools for purposes of experimentation and scientific research.[37] Litigation arose out of the will provision requiring that "no funeral services be held." Both the surviving spouse and children objected to the provision and requested that a brief and simple service be held. The executor of Metalious' estate asked for a court order prohibiting

the service because it was a violation of the deceased's express intentions.

In deciding to permit a funeral service, the New Hampshire court recognized the general principle that the surviving spouse and next-of-kin (in that order) are given a limited property right in the body to determine matters relating to the burial, at least in the absence of a contrary direction in a decedent's will. While recognizing that an individual's wishes might take precedence over the opposing wishes of others, the court noted that "rights in matters of burial or disinternment are not absolute and will be governed 'by rights of propriety and reasonableness. . . . '" Because Metalious had coupled her desire not to have funeral services with the attempted donation of her body to the medical schools, the court reasoned that, because of the failure of the primary objective (donation of her body for medical research), it was not unreasonable to conclude that the wishes of her spouse and children should take precedence.[38]

While the Metalious decision favored the wishes of next-of-kin, it contained important language suggesting that, under ordinary circumstances, the expressed intentions of the deceased should take precedence.[39] The oblique reference to "ordinary circumstances" is interesting in this case. The only apparently "extraordinary" element was the fact that Grace Metalious was famous and much in the public eye.[40] More important, however, is the court's recognition of the fact that, in light of medical advances, the existing law regarding anatomical dispositions was inadequate and that there was an urgent need for an appropriate statutory mechanism

to ensure the implementation of the desires of the dying to aid the living.

2. THE UNIFORM ANATOMICAL GIFT ACT

As noted above, the common law provided no mechanism for donating tissues, organs, or cadavers for medical use or experimentation. Donations by next-of-kin who had a legal right to dispose of the body were frequently inhibited by the uncertainty inherent in the law.[41] Even today, anatomical gifts through wills are not considered to be final testamentary dispositions and may be defeated by a surviving spouse or close relative.

The need for human tissue and body parts for experimentation, education, and transplantation led many states to enact donation statutes in the 1950's and 1960's. Although they were a significant advance over the common law, they were beset with a number of legal and practical problems; they varied in their content and coverage, were often inadequately drafted, and generally served to create a great deal of confusion regarding the execution of testamentary anatomical gifts.[42]

In response to this situation, the Commission on Uniform State Laws appointed a subcommittee to "study and report on the subject matter of a Uniform Gifts of Human Tissues Act."[43] The final act, approved by the Commission in 1968,[44] was designed to provide a favorable legal mechanism for encouraging and facilitating the donation and use of human cadaver parts. Thus, the Uniform Act generally provides that:[45]

> any individual of sound mind and 18 years of age or older may give all or any part of his body for any purpose specified in section 3, the gift to take effect upon death.

Donation may be made to any hospital, surgeon, physician, accredited medical or dental school, college or university, organ bank, or storage facility, or specified individual for use in education, research, the advancement of medical or dental science, therapy, or transplantation. Currently, all 50 states and the District of Columbia have enacted their own legislation that very closely parallels the provisions of the Uniform Act.

The preface to the Uniform Act notes that, if the effective utilization of organs and bodies is to be accomplished, there are a number of competing interests and needs to be weighed, and legal questions that need to be answered. The competing interests that create potential problems for organ donation include the:

(1) wishes of the deceased during his or her lifetime regarding the disposition of his or her body;

(2) wishes of the surviving spouse and/or next-of-kin;

(3) interests of the state in determining (through autopsy) the cause of death in cases involving crime, violence or unusual circumstances;

(4) need to determine the cause of death (through autopsy) when private legal rights are dependent upon the cause; and

(5) need of society for bodies, tissues, and organs for medical education, research, therapy, and transplantation.

The conflicts between competing interests inevitably raise serious legal questions that must be overcome to facilitate resolution. The most important legal questions raised by organ donation include:

(1) Who may, during his or her lifetime, make a legally effective gift of his or her body or organs?

(2) What are the legal rights of next-of-kin, either to overturn the expressed wishes of the deceased, or to make anatomical gifts from the dead body?

(3) Who may legally be the recipients of anatomical gifts?

(4) For what purposes may anatomical gifts legally be made?

(5) How may anatomical gifts legally be made (e.g., by will, by other writing, by a signed and witnessed donor card, by telegraphic or recorded telephone communication)?

(6) How may an anatomical gift be legally revoked by the donor during his or her lifetime?

(7) What are the survivors' legal rights relative to the body after the removal of donated parts?

(8) What protection from legal liability should be afforded to persons (including surgeons and others) involved in carrying out anatomical gifts?

(9) Should such protection extend nationwide, regardless of the state in which the anatomical gift was made, i.e., how should conflicts between the laws of different states be resolved?

(10) How should conflicts with state autopsy laws be resolved?

(11) Should the manner of determining the time of death be defined by law?

(12) Should the interest in preserving life by the physician in charge of an organ donor preclude him or her from participating in the transplant decision-making process and procedure?

The following sections discuss how the Uniform Act attempts to resolve competing interests in dead bodies and addresses the legal questions raised by organ donation.

a. Formal Requirements. In general, any person of sound mind who is 18 years of age or older,[46] may give all or any part[47] of his or her body for medical or dental education, the advancement of medical or dental science, research, therapy or transplantation.[48] The gift may be made in the donor's will, and becomes effective upon his or her death without waiting for the will to be probated.[49] Alternatively, the gift can be made through a document other than a will.[50] However, if the gift is made through a document other than a will, the donor must sign the document in the presence of two witnesses who must also sign the document.[51] If the donor fails to meet the witness requirement, the error can be corrected by the donor's family, which may donate the body by means of a document or recorded communication.[52] Similarly, attempted anatomical gifts that fail because of the donor's youth or lack of mental capacity may be corrected by the donor's family.

The provision for correcting errors in attempted gifts provides a mechanism to ensure that the donor's express wishes are carried out. In addition, correction is made easier by the elimination of the witness requirement. A correction can be made through a document signed only by a family member.[53]

Amendment/revocation of an anatomical gift. A gift, whether made through a will or other written document, may be amended or revoked by the donor.[54] If the potential recipient was notified

of the intended gift, it may be revoked or amended by delivering a signed statement to the donee,[55] or by communicating to the donee an oral statement made in the presence of two witnesses.[56] If notice of the proposed gift was never given to the recipient, it may be revoked by destroying all copies of the gift document[57]

Specifying recipients. A donor may make an anatomical gift with or without specifying an intended recipient. However, the Uniform Act does limit specified recipients to any physician, surgeon, hospital, medical school, dental school, college or university, bank or storage facility, or any specified individual for therapy or transplantation needed by him or her.[58] If the donor does not care who receives the gift, or if he or she simply states the intention to make an anatomical gift, the attending physician may accept the gift as a legal recipient and transfer the body to another eligible donee whom he or she knows needs it.[59] It should also be pointed out that any donee, whether specified or not, is entitled to reject an anatomical gift.[60]

Specifying physicians to perform removal or transplant. The donor may specifically designate the physician or surgeon who is to perform the appropriate procedures for removing or transplanting a donated body part.[61] If the donor does make a specific request or if the designated physician is not available, the recipient may authorize any physician to perform the necessary procedures.[62] However, if the attending physician becomes the legal recipient (either because the donor did not specify a recipient, or because the specified recipient is unavailable), he or she could not participate

in the removal or transplantation procedures,[63] because the Uniform Act specifies[64] that the physician who certifies the donor's death may not participate in them. This provision is intended to remove any appearance of conflict of interest between the need for transplantable organs and the declaration of the potential donor's death.

Funeral and burial arrangements. The Uniform Act provides that the recipient of a donated body may, subject to the overall terms of the gift, authorize the embalming and use of the body in funeral services.[65] Depending on the wishes of the donor, this authority may be invoked by the recipient to prevent funeral arrangements that would make the body useless to the recipient.[66]

Protection from liability. Section 7(c) provides that "a person who acts in good faith in accord with the terms of this Act or with the anatomical gift laws of another state (or a foreign country) is not liable for damages in any civil action or subject to prosecution in any criminal proceeding for his act." This provision provides broad protection to anyone (including next-of-kin, funeral directors, medical examiners, or attending physicians) who acts in good faith or belief that a donation was intended or has been made, even if the gift has been revoked or amended. In the absence of such protections, physicians would be reluctant to remove organs or tissues without having certain confirmation of the latest intentions of the donor. Because of the need for speed, such hesitancy would defeat the purpose of the Uniform Act.

3. UNANSWERED QUESTIONS UNDER THE UNIFORM ACT

The Uniform Act was not intended to be a panacea for all of the legal and medical problems inherent in the transplantation process. As with other uniform acts, its express focus was on what each individual state could do to satisfy its own needs while respecting the rights and interests of other states. In furtherance of this broad goal, the Uniform Act did not attempt to address a number of important questions, including the declaration of time of death, the allocation of transplantable body parts, and the sale of, or payment for body parts. Each of these are discussed more fully below, but a brief mention here of the issues they raise is important for understanding other potential mechanisms to ensure an adequate supply of donor organs.

a. Time ofDdeath. The Uniform Act deliberately made no effort to define that specific point in time (if, in fact there is such a point) when life ceases to exist. The comments to Section 7(b) illustrate the approach taken by the Act:[67]

> Subsection (b) leaves the determination of the time of death to the attending or certifying physician. No attempt is made to define the uncertain point in time when life terminates. This point is not subject to clear cut definition and medical authorities are currently working toward a consensus on the matter. . .The real question is when irreversible changes have taken place the preclude return to normal brain activity and self sustaining (sic) bodily functions. No reasonable statutory definition is possible. The answer depends upon many variables, differing from case to case.

As we discuss later, it is apparent however that no medical consensus has yet been reached on the matter.[68] But the issue of when an

individual is "dead," is critical to the effective functioning of a donation system. "To delay too long, so that metabolism ceases and tissue is damaged, can be fatal to the recipient. To act precipitately, when there is still possibility of restoration of the donor is unthinkable."[69]

b. Allocation of Human Tissue and Organs. Similarly, the Uniform Act did not attempt to address the issue of the mechanism of allocation of body parts among potential recipients. As we have noted elsewhere,[70] the selection of recipients for scarce human body parts raises profound legal, ethical, and moral problems. After general factors such as tissue typing and the general medical suitability are taken into account, there are a number of alternative methods that can be used to allocate organs among recipients, including selection by first -come-first serve, random choice by lottery, ability to pay, age, use of predetermined social worth criteria, and determination by the individual in possession of the organ.

c. Sale of Organs. Finally, the Uniform Act does not refer to the frequently mentioned alternative of the sale of organs for transplantation. Although there is considerable sentiment against this process, the Uniform Act does not specifically prohibit it. However, the Act's use of terms such as "gift," "donation," and "donor" strongly implies a nonprofit orientation. Its silence presumably indicates an assumption that the matter is best dealt with, if at all, in a different forum. As we discuss below, the widespread acceptance and use of paid donors for blood transfusions and blood banking may portend similar developments in organ transplantation,

especially as organ preservation techniques improve and the demand for transplantable organs grows.

4. THE INADEQUACY OF THE UNIFORM ACT

Despite its nationwide implementation, the Uniform Act has not provided a sufficient number of organs to meet the demand arising out of transplantation and therapy. Some commentators[71] argue that it is too early to bring in such a verdict and that, with time and a further increase in the public's consciousness, the donation system will produce an acceptable number of organs. Although a number of states have enacted legislation that requires the furnishing of a donor card with a driver's license, or print the donor card on the back of the license, there is no evidence that the number of donations has increased to any significant degree.[72] A number of reasons have been offered for the apparent failure of the Uniform Act, most of which center on the psychological difficulties inherent in dealing with the prospect of ultimate and inevitable death. It has been recognized that the Uniform Act is procedurally superior to the confusing group of individual state statutes that preceded it.[73] With that advantage, however, came the realization that the substance of donative mechanisms still failed. Thus, ". . . is not there something macabre about a society where people walk around with little cards saying they have donated their organs on death to so-and-so?"[74] The sense of the macabre may stem from the psychological difficulty of dealing with one's own death. As long ago as 1925, Freud wrote that:[75]

> Our own death is indeed unimaginable, and whenever we make that attempt to imagine it we can perceive that we

> really survive as spectators. Hence, . . . at bottom no one believes in his own death, or to put the same thing in another way, in the unconscious every one of us is convinced of his own immortality.

Among a number of other reasons of lesser importance, it may be that the generalized fear of death extends to the reluctance to sign and carry organ donor cards.

A recent survey of nationwide organ procurement practices highlights the inadequacy of current donation and procurement practices.[76] Responses to the inquiry revealed a number of fallacies and misconceptions concerning practices under the UAGA. One of the most important findings of the survey was the explicit belief among respondents that a greater number of signed donor cards would necessarily increase the supply of donor organs. However, the fact that only a small percentage of donors actually have such cards raises questions about current methods of donor card distribution and their overall effectiveness.

Second, the survey pointed out what was obviously suspected--hospitals and organ procurement programs differ in their degree of success at obtaining organs for transplantation.[77] The inquiry indicated, however, that the greatest difference between such programs is not <u>how</u> potential donors are identified, but rather <u>how consistently</u> (or persistently) programs attempt to do so.[78] Effective efforts to procure organs generally involve the establishment and maintenance of a network of referral sources within the medical community.

As revealed by the survey, perhaps the greatest difficulty in maintaining a reliable referral network lies in changing the attitudes

both of the medical community and the general public. Generally, respondents felt that physicians should be more sensitive to the need for organ procurement and more supportive of efforts to do so. Respondents also felt that the general public should be informed about the benefits of organ transplantation, the critical need for transplantable organs, and the noble purposes that can be served by organ donation. Such an effort would, it was felt, significantly ease the burden of organ procurement and increase the ability of organ procurement programs to meet the demands placed on them.

Third, the provisions of the UAGA are largely ignored in regard to consent to donate. Although the UAGA explicitly recognizes donor documents as sufficient legal evidence of an individual's donative intent (and extends blanket immunity to those "acting in good faith" in regard to organ procurement), the vast majority of medical institutions do not allow organ removal without the consent of next-of-kin. While the underlying philosophy of the UAGA is to facilitate the expression of an individual's intent to donate, the reality is that such intentions will not be carried out unless, and until, a family member consents. In the majority of instances, this policy was based on fear of prosecution or malpractice liability. The medical and transplant communities simply do not feel that the provisions of the UAGA provide sufficient protection.

Finally, the survey suggests that legislation alone would not remove all of the perceived barriers that stand in the way of efficient organ procurement. There remains the question of how to deal with ethical objections to the removal of organs from an

individual who has not expressed an intention to donate or whose next-of-kin object in the face of such an intention.[79] Regardless of the specific approach taken, the resolution of these troubling problems will involve a considerable investment of time and resources in education, both professional and public.

In this view, it is interesting to note that in 1967 a Gallup poll indicated that 70% of the American population would be willing to donate their organs after death. In the February 1983 National Kidney Foundation Poll, 40% of the people polled were "very likely" or "somewhat likely" to donate, but only 26% were "very likely" to donate their own kidneys. Yet 72% were "very likely" to give permission to have the kidneys of a relative or loved one donated after that person's death. Two interesting points are raised by these figures. First, there is some indication that the willingness of individuals to donate has declined overall. However, any conclusions are tentative at best until the specific questions and data from both surveys are carefully analyzed. Second, the evidence strongly indicates that people are more willing to consent to the donation of someone else's kidneys than to their own. This finding suggests some important psychological and attitudinal issues, which are addressed below.

By way of contrast, however, compare these figures to the extremely small number of people who actually carry donor cards, and the even smaller number whose donated intentions are actually carried out.[80] The inconsistency between expressed intention and actual behavior has led one commentator to conclude that the only solution:[81]

> is that any organ donation statute should infer the consent of decedents to the removal of their organs because seven out of ten Americans favor organ removal, and because it is unrealistic to expect these people to take the steps currently needed for an organ donation when such a procedure causes fearful anxiety.

Transplant coordinators are, perhaps, the best source of information about the difficulties in obtaining organs for transplantation. Their experience and efforts to facilitate donations have led to the identification of a number of impediments to progress.[82]

a. Approaching the Bereaved Family. A major impediment in the way of obtaining donor organs, is the natural reluctance of medical personnel to approach the family or next-of-kin of the dead person to request the donation of organs. Although these attitudes may be subject to change through experience and education, they are extremely personal and likely to be highly resistant to change. Similarly, the physician may have doubts, both personal and medical, about approaching the dying patient about organ donation. The physician must be certain of the prognosis, and must confront the task of telling the patient about the hopelessness of his or her case.[83]

b. Destruction of Hope. There is also considerable reluctance to destroy the hope of a dying patient by asking him or her to donate organs. As a countervailing factor, however, some authorities suggest that the ability to maintain control over events (especially events having to do with ones personal autonomy) is important to the dying patient.[84] From this perspective, making an

anatomical donation may be the last chance that the patient has to exercise such an impact and degree of control.

In addition to specific problems not addressed in the Uniform Act, there are two other general categories of problems that are important in undermining the success of donation as an organ procurement mechanism. These problems relate both to logistics and attitudes in the medical community.

c. Logistics. The most important aspect of logistics is that channels of medical communication have not kept pace with the demands imposed by technological advances in medicine. Despite the presence of organ procurement agencies and their efforts to supply donor organs, most transplantation occurs in the large medical centers and the average physician simply is not a part of that communication network.[85] Neither the average physician nor transplant teams have much interaction with each other, and the need for donor organs is not adequately communicated. A related aspect of this communication problem is that local physicians are often reluctant to refer patients (who may be potential donors) to large hospitals where the physician does not have personal acquaintances. Because the potential donor is not attended by a transplant team, the gap between donation and implantation may be lengthened, often beyond the time in which the donor organ may be used.[86]

d. Attitudes. Attitudes apparently held by many physicians interfere in their effective participation in the organ procurement process. These include the physician's attitude toward:[87]

(1) the dying patient as a reflection of his or her own personal and professional failures;

(2) the appropriateness of revealing to the patient his or her impending death;

(3) heroic life-saving medical procedures;

(4) the definition of death; and

(5) the role he or she should play in the management both of the patient's and next-of-kin grief.

All of these attitudes interact with the characteristics of the patient (and his or her family) to influence the extent to which the physician will become involved in organ procurement. It is important to note, however, that physician involvement in organ procurement (especially obtaining consent from the next-of-kin) may have its limitations. There is evidence that physicians are not successful in approaching next-of-kin. One transplant center reported a 45% success rate for physicians in 1981, and a 20% success rate in 1982; these figures compare unfavorably to the overall 75% successful permission rate obtained by organ procurement specialists.[88] It appears that the majority of practicing physicians do not have the time, skills, nor commitment to effectively pursue organ procurement.

Because so few people make prior arrangements for organ donation, many donations must be sought after the patient's condition has become hopeless, but before he or she is dead. If donation arrangements can be made with the patient taking an active role, the process is facilitated. Unfortunately, requesting an organ donation from the patient can be extremely traumatic for the physician, the patient, and the next-of-kin who may be involved.

For the physician, the difficulty is that he or she must be certain of the prognosis of death, and must make the effort to communicate to the patient the hopelessness of the situation. While research[89] indicates that for the most part, patients want to know the truth about their conditions, many physicians strongly resist such an approach for fear of causing psychological (or physical) harm to the patient. It may also be that the physician resists confronting the death of a patient out of denial of death itself, or because the patient's death is seen as a failure by the physician. In any event, requests are often not made while the patient is still alive, and the burden of decisionmaking is shifted to the next-of-kin upon the patient's death.

As can be seen, the UAGA is an attempt to resolve a situation rife with legal, social, and ethical problems. It attempts to strike a workable balance between and among the competing interests of groups and individuals affected by transplant technology and the need for organ procurement. We have noted that there are a number of issues that remain unresolved within the context of the UAGA and voluntary organ procurement. The sensitive legal and social nature of these issues was explicitly recognized by the drafters of the UAGA, and the decision was made that their resolution was outside the scope of the model act. The data that do exist suggest that voluntary organ procurement under the UAGA has not been given a full and fair trial. It is suggested that there are a number of ways (e.g., through public information, and more active state government involvement) to improve the performance of voluntary organ procurement. Other commentators

suggest, however, that reliance on donation will not meet the need for transplantable organs, and that alternative methods of supply are needed. The following sections examine these alternatives.

D. ALTERNATIVES TO THE UNIFORM ACT

In considering alternatives to the Uniform Act it is important to keep in mind the interests that the Act attempts to balance. These include: (1) the individual's interest in the disposition of his or her body after death, (2) next-of-kin's interest in possession of the person's body after death for purposes of religious ritual and burial, (3) society's interest in determining and verifying causes of death,[90] (4) society's interest in obtaining cadavers for medical education and research, and (5) society's interest in the procurement of adequate tissue and organ resources for transplantation and other lifesaving therapy. All of these interests have been advanced through a variety of laws and judicial decisions regarding burial, post mortem examinations, and cadaver donation. While the Uniform Act was an attempt to address society's interest in cadavers and organs as limited and valuable resources for transplantation and medical study, the existing data suggest that the UAGA has been less than an overwhelming success. An important question, then, is how the interests in cadavers can be considered in a way that will more adequately meet the need for transplantable tissue. This section examines the general categories of organ procurement approaches that form the basis for alternatives to reliance on voluntary donation, including routine removal in the absence of objection, compulsory

removal, and a market system for transplantable organs. The specific focus of the discussion will be on the legal implications that flow from each alternative.

1. REMOVAL IN THE ABSENCE OF OBJECTION

Currently, one of the most popular alternatives to donation involves routine removal of organs for transplantation unless the decedent has made his or her objection to removal specifically known, the so-called "opting out" procedure.[91] A variation of opting-out would permit next-of-kin to interpose their objections to removal after death (but only if the wishes of the decedent were not specifically known, i.e., next-of-kin could not prevent removal if the person had given consent before death).

Appendix 32-A presents the text of a proposed law that would allow the removal of organs for transplantation in the absence of objection.[92] It is argued that the proposal would satisfactorily meet the goals outlined above, i.e., it would (1) protect the person's wishes regarding the disposition of his or her body after death, (2) safeguard the objections and wishes of next-of-kin, (3) protect the bodily integrity of living persons, and (4) help ensure an adequate supply of needed organs and tissue for transplantation.

The proposal allows the individual to object to organ removal and provides a mechanism to facilitate recording and communicating objections. To alleviate potential problems arising out of coercion, the proposal[93] provides that the revocation of an objection is not effective until 30 days after it has been filed. In other words, the provision resolves all doubts in favor of the individual's decision to

object to removal. Once an objection is filed, it cannot be over-turned during the time the individual is on his or her deathbed.[94]

The interests of next-of-kin are recognized in Section 8 in the establishment of priority classes of persons who may object to removal. Note that the proposal does not provide for an affirmative attempt to notify next-of-kin. The reason for the absence of such a provision is the critical nature of time in the removal of organs for transplantation. The requirement to notify the next-of-kin may make the difference between salvaged and unusable organs. Increased ischemic[95] time may also significantly reduce the probability of a successful transplant procedure.

The legal issue is whether the failure to provide notification violates the next-of-kin's constitutional right to due process by law. There is some evidence that next-of-kin have some right, or at least "expectancy" of a right in the body of their dead relative.[96] However, that right likely could be revoked by a statute, as could next-of-kin's right to object to organ removal.

Even if it is determined that the next-of-kin have some property right to the decedent's body, the answer to the question of whether due process requires notice must balance the interests involved, i.e., will the injury to next-of-kin who are not notified (and thus have no chance to object) outweigh the public good to be gained in having a rapid decision regarding the disposition of valuable organs? The fact that the decedent presumably had no objections must also be entered into the equation. Under these

circumstances, a strong argument could be made that next-of-kin interests should not override the advantages to the public welfare.

To help alleviate the notice problem, opting-out proposals include the formation of a registry where objections may be recorded. In practice, however, a registry would do little to overcome these problems. First, family relationships change rapidly through death, divorce, and marriage and each such change would require a new data set. Second, modification of the extent and scope of a person's objection would also be cumbersome; each such change would require a report to the registry. Third, creation and maintenance of an objection registry would be costly and time-consuming. Finally, a registry would impose an additional burden on physicians and transplant personnel, forcing them to use an additional mechanism that may not be up-to-date, rather than underlying on a donor card or the good graces of next-of-kin.

2. COMPULSORY REMOVAL OF CADAVER ORGANS

A second approach involves the compulsory removal of cadaver organs whenever needed for medical purposes. While there is little doubt that such a system would increase the number of organs available for transplantation, it would do so only at the expense of a number of important legally protected interests of both the decedent and his or her next-of-kin. Infringement on these interests is important because:

(1) it may effect on public attitudes toward medical innovation;

(2) of the likelihood of enactment by state and/or federal legislation; and

(3) of the probable conflict and protections guaranteed in the Constitution.

Such a proposal could be challenged under at least three fundamental constitutional principles: freedom of religion, due process, and eminent domain.

a. Freedom of Religion. The First Amendment prohibits the enactment of laws that forbid the free exercise of religion. The Supreme Court has applied different tests of validity to laws that restrict free exercise, depending upon the nature of their effect on the exercise of religious choice, i.e., whether they burden religious choice directly or indirectly. Direct infringement has been found when a law prevents an individual from engaging in practices that are required by his or her religious beliefs. Such laws are generally based on a desire to eliminate religious practices that are considered to be socially harmful.[97]

The Supreme Court has considered direct burdens on free exercise of religion in the context of four different areas: health and public welfare, compulsory military duty, compulsory jury duty, and compulsory patriotic oaths.[98] The first significant case in which the Court upheld public welfare legislation that had a direct burden on the practice of religion involved the conviction of a Mormon for polygamy. The Court considered such conduct to be repugnant to the moral standards of the nation and dangerous to the community concepts of peace and good order.[99] In In re Jenison,[100] a Minnesota court held that a woman could not be compelled to serve on a jury when her religious principles dictated that she not "judge" her fellow citizens. The Court decided that the public interest in finding competent jurors would not be significantly interfered with if

religious objectors were exempted from jury duty. The state's interests were simply not sufficient to allow such a burden on the individual's right of free religious expression.

Indirect burdens on freedom of expression have been found when a law makes it more difficult or expensive to comply with a set of religious beliefs, even though no religious practices are absolutely prohibited. Thus, in Braunfeld v. Brown,[101] an Orthodox Jew contended that a Sunday closing law for businesses forced him to choose between keeping his business open on a Saturday (and breaking the Jewish Sabbath) and going broke. The Court did find that the law put a burden on his free exercise of religion, but upheld the statute. The Court noted that:[102]

> If the state regulates conduct by enacting a general law within its power, the purposes and effect of which is to advance the state's secular goals, the statute is valid despite its indirect burden on religious observance unless the state may accomplish its purposes by means which do not impose such a burden.

Thus, if a legitimate state goal can be accomplished without burdening the free exercise of religion, a law that burdens it, even indirectly, is invalid.

If an individual believes that his or her faith requires burial intact, a compulsory removal law would make it impossible (not just difficult) to adhere to religious principles. Such a direct burden on free expression could be justified only if a court found that there was an overriding need for a large supply of organs for transplantation, and that the procurement of organs was a proper arena for state involvement. On the other hand, for indirect burdens on

free expression, a state adopting a compulsory removal statute would have to show: 1) that an adequate number of cadaver organs could not be obtained without interfering with free expression, and 2) that alternative legislative approaches would not yield a sufficient number of organs to meet the demand.

In the absence of a demonstrated and compelling need for cadaver organs that could not be obtained through some other means, a compulsory organ removal law would likely face serious challenges as an infringement on the free expression of religion. In addition, the protections afforded under this doctrine could be broadened to cover any individual who expressed a moral objection to organ removal, since there is case law to suggest that courts may consider deeply held and sincere moral and ethical beliefs to fall within the realm of religion.[103]

b. The Right to Privacy. Like the right to control and disposition of one's body, the right to privacy is not encompassed within the textual framework of the Constitution. Yet it has a long and important history in American jurisprudence. Justice Brandeis summarized the principles underlying the right to privacy in 1928, when he wrote that:[104]

> The makers of our constitution undertook to secure conditions favorable to the pursuit of happiness. They recognized the significance of man's spiritual nature, of his feelings and of his intellect. They knew that only a part of the pain, pleasure and satisfactions of life are to be found in material things. They sought to protect Americans in their beliefs, their thoughts, their emotions and their sensations. They conferred, as against the government, the right to be let alone--the most comprehensive of rights and the right most valued by civilized men.

While still a lower court judge, Chief Justice Burger amplified this doctrine, noting that:[105]

> Nothing in this utterance suggests that Justice Brandeis thought an individual possessed those rights only as to sensible beliefs, valid thoughts, reasonable emotions, or well-founded sensations. I suggest he intended to include a great many foolish, unreasonable and even absurd ideas which do not conform such as refusing medical treatment even at great risk.

It is with regard to rights such as privacy that courts have long held that the government's purpose to control or prevent activities that are constitutionally subject to state regulation can not be achieved by means that are unnecessarily broad and infringe on protected areas of behavior.

Whether the right of an individual to control the disposition of his or her body after death, or the right of the next-of-kin to control the disposition of the body of a recently deceased family member are rights so fundamental that they could not be overridden by a compulsory organ removal statute is unclear. Suffice it to say that such rights have yet to be considered "fundamental" (in the constitutional sense), and the Supreme Court historically has been loathe to extend such status to any right not specifically enumerated in the Constitution.

In summary, whether one views the rights to ones body as absolute, or is most concerned with the desirability of fostering a community a social relations based on affirmative consent, or places great emphasis on preserving fundamental individual rights (such as freedom of religion and the right to privacy), it is clear that the

system of voluntary donation through consent has legal, social, and ethical advantages over any other system discussed. Whether these interests should ever be subservient to the interests of society is a difficult question; and a question that can only be avoided or postponed if the need for transplantable organs can be satisfied by consensual donation.

c. Eminent Domain. The Fifth Amendment to the United States Constitution,[106] and similar provisions in most state constitutions require the payment of "just compensation" whenever the government takes private property for public use. The questions to be considered in the context of compulsory organ removal are: 1) whether the involuntary removal of cadaver organs constitutes a "taking" of property for public use, and 2) what kind and amount of payment will satisfy the just compensation requirement.

One of the most difficult problems in analyzing eminent domain cases involves the definition of "taking." Whether a particular government act requires compensation often turns on the label that the court attaches to the act. If the act constitutes a "taking," compensation will have to be paid; however, if it merely amounts to a legitimate government regulation, no compensation is required. The two most important legal tests of taking involve two discrete conceptual distinctions. One test focused on whether the government had asserted a "proprietary" interest in the private property.[107] The other emphasized the "diminution of value" of the property as a result of the government's actions.[108]

Regardless of the test employed, however, the physical invasion of private property has always been regarded as a taking. Even when the physical invasion is minor, a valid claim for compensation has been found.[109] Thus, the involuntary removal of cadaver organs would appear to be an exercise of eminent domain sufficient to require compensation. However, before concluding that a claim for compensation will arise, it is necessary to examine the nature of the rights affected when the state takes a cadaver organ for transplantation. In some cases[110] governmental action that might otherwise constitute a taking has not required compensation because the claimant has been found to have no property interest in the thing invaded.

In general, courts have recognized the right of survivors of a deceased to custody and control of the dead body.[111] This right enables the family of the deceased to possess and "bury the body as it was when life became extinct."[112] Thus courts have held that the next-of-kin has standing to sue to require a decent burial of the corpse and to recover damages for any interference with that right.[113] Similarly, recovery has been permitted when organs have been removed and retained following an autopsy, whether lawfully performed or not.[114] In addition, the common law has never recognized any commercial rights in a dead body,[115] and as a result, the rights of the next-of-kin of a deceased have never been accorded any economic value. However, in giving the next-of-kin possession and control of the body, courts have often spoken of their rights as amounting to a property or quasi-property interest.[116] In sum,

there is a good chance that courts would regard the compulsory removal of cadaver organs as a taking of private property.

Any statute authorizing the exercise of the eminent domain power must satisfy the public use requirement of the federal and state constitutions. Two tests have been used to define public use. The first has been called the "public benefit test," under which public use is construed to mean public advantage; that is the use of property in such a way as to advance the health, safety, and welfare of the community. In essence, this test equates the power of eminent domain with the police power of the state.[117] The second test used to define public use represents a more restrictive view under which the public must be entitled (as of right) to the common use of the property taken. As originally applied, the strict application of this test would have denied the state the right to compulsory removal of organs, since the "public" would not have been able to enjoy the common use of the property. Over the years, however, the doctrine has lost much of its original form and strictness of application, because courts have taken the view that although a benefit may be used by only a few, the benefit will accrue to the public as a whole (i.e., low income housing). Finally, narrow application of the doctrine has been weakened by certain traditional exceptions to the public use requirement. Chief among these is the "special circumstances" exception that basically states that where unusual conditions exist in a particular state, making certain activities vital to its economic well-being, property may be taken for purposes that would otherwise be considered unlawful.[118]

In sum, considering the overriding interest of the state in preserving the lives of its citizens, it may be possible for a court to uphold a compulsory removal law against charges that no public use is present. The basic purpose of the public use requirement--to prevent governmental excesses by disallowing taking where the objective is a purely private gain--would not be present under a statute by which all of society stands to gain.[119] The question then arises whether the public use requirements is satisfied when a taking is affected in order to benefit the citizens of another state. If benefiting people outside of the state is not considered a public use, and since at the time of taking it may not be known to whom an organ will be given, it may be argued either that the statute is invalid as a whole or that organs taken under it may only be used by citizens of the taking state.

As noted above, it appears that a next-of-kin would have a compensable claim if a decedent's organs were compulsorily removed by the state. The question is how such compensation is to be determined.. Traditionally, when the property taken has a determinable market value, it is used to establish the rate of compensation. When no ready market exists, the courts have often used a concept related to the "intrinsic" value of the property as a benchmark. This value may be determined by considering such criteria as age of the property, condition, location, original cost, and adaptability. A variation of this rule is the "value to the owner test," which takes into account the owner's personal use of the property.

It goes without saying that either of these tests is nearly impossible to apply to the case of transplantable organs that have never been bought and sold in the market. The difficultly is not so much that there is no market for such organs, but rather that the courts have consistently refused to recognize any commercial rights in the property right of the next-of-kin in the dead body. The absence of a market value for transplantable organs results more generally from a policy determination on the part of the courts that commercial dealing in dead bodies and body parts would be offensive to the public's sensibilities, not that the body part lacks a natural market. It is the former issue that will undoubtedly stand in the way of any consideration of compulsory organ removal.

3. A MARKET SYSTEM FOR TRANSPLANTABLE ORGANS

A third alternative to the present donation system involves proposals for the development of a market-based system for the sale and purchase of organs for transplantation.[120] The basic assumption of a market system is that a sufficient number of individuals would be enticed by financial rewards to contract for the sale of their body parts so that overall supply would be increased. In the ideal situation the forces of supply and demand would operate to maximize the number and kind of organs available.

A market-based approach to meeting the demand for transplantable organs has a number of important advantages over other mechanisms that have been suggested. For example, because consent to buy and sell would remain a paramount concern, a market system would significantly increase the supply of organs without sacrificing the

individual's ability to control the disposition of his or her body.[121] In addition, because a market-based system would encourage people to plan ahead for the disposition of their bodies, much of the friction between physicians, patients, and relatives at the time of death would be eliminated.[122] Thus:[123]

> The previously executed contract would enable the transfer to be accomplished at death with no further questioning of the patient or his relatives. Even those who decide not to enter into a sales contract would benefit, for, if the scarcity problem is eliminated by organs provided by people who do contract, those who have not contracted would not be pressured by agents for the needy.

A market system for the transplantation of human organs is not, however, without problems. The implementation of such a concept may encounter severe ethical objection. One of the major concerns may be that only the poor and powerless will sell their body parts and only the wealthier upper class will be able to purchase them. It should be noted, however, that this criticism has also been raised in regard to the present donative system.[124]

A second objection to a market system could be raised by those who disapprove on moral grounds of any system that encourages the sale of human body parts. Fears of "unsavory trafficking" are brought to mind, and visions are conjured up of the business made famous by the notorious Edinburg murderers, Burke and Hare who killed 16 people and sold their bodies to medical institutions for dissection. Consider the remarks of Titmuss on the nature of the commercialized blood market:[125]

> The commercialization of blood and donor relationships represses the expression of altruism, erodes the sense of community, lowers scientific standards, limits both personal and professional freedoms, sanctions the making of profits in hospital and clinical laboratories, legalizes hostility between doctor and patient, subjects critical areas of medicine to the laws of the market place, places immense social costs on those least able to bear them--the poor, the sick and the inept, increases the danger of unethical behavior in various sections of medical science and practice, and results in a situation in which proportionately more and more blood is supplied by the poor, the unskilled, the unemployed, negroes and other low income groups and categories of exploited human populations of high blood yielders.

In this regard, however, Sale notes that it is not mercenary or unethical for an individual to buy life insurance -- and the sale of one's body parts before death (perhaps with the proceeds to go to one's beneficiaries) has a benefit not found in life insurance: it provides life-saving organs for other individuals. It goes without question, however, that a market system for transplantable organs has troubling implications. For instance could a debtor put up his or her kidney as collateral for a loan or could a person be forced to sell a kidney in order to satisfy a money judgment? A number of such abuses are possible within a market system and it seems reasonable to assume that an organ market would have be regulated to protect against them.

Sale[126] outlines at least five kinds of transactions that could take place in a market system for transplantable organs. These include:

> (1) A present contract for the right to the body (or to specific body parts) upon the death of the seller, with remuneration to be paid upon death to name the beneficiaries (or to the seller's estate). In such a transaction the remuneration

is not determined until the body is actually available for use, i.e., at death, and its value ascertained.

(2) A present contract for the right to the body (or to specific body parts) upon the death of the seller with a definite remuneration guaranteed at death to a named beneficiary (or to the seller's estate). Such a transaction requires the buyer to accept a degree of risk with respect to the value of the parts for which he or she has contracted.

(3) A present contract for the rights to the body (or to specific body parts) upon the death of the seller, with payment to be made at the time of the contract. Such a transaction would again require the buyer to accept a degree of risk regarding the value of the seller's parts.

(4) A present transfer of non-vital organs and tissues (such as kidneys and skin) from a living seller for present remuneration.

(5) A sale by the next-of-kin of the decedent's body part after the decedent's death.

The first and second proposals provide, in effect, zero premium life insurance policies. Payment is made upon the death of the seller to designated beneficiaries. In the first proposal the amount paid will be uncertain but it may have a bottom limit on the worth of the cadaver. In the second proposal beneficiaries would receive a specified amount.

The fourth proposal, that present payment be made for the present transfer of non-vital organs, has the disadvantage of permitting an individual to subject him or herself to a health risk for a strictly financial return. There are a number of objections to such proposals. For instance, many physicians are hesitant to use living donor sources. The donor psychological benefit which has been

used to justify transplant from living sources is harder to accept when the major motive for donation is clearly monetary. In addition, living donors may be subject to considerable family and self-imposed pressures that make free consent improbable. Finally, the addition of a money incentive may also be coercive--if an individual's financial need is great enough, his or her rational assessment of the affect of organ removal on his or her future health may be impossible.

The fifth alternative is the sale of a decedent's body by the next-of-kin could be either subject to a decedent's right to object by expressed statement before death or allowed regardless of the decedent's wishes. Either approach may be objectionable because sale by the next-of-kin offends the traditional concept of respect for the dead. The fifth alternative may even lead to the sale by expectant heirs of the rights to a individual's body parts before he or she has died. The objection that the sales concept is too mercenary is of particular importance here. Moreover, a failure to give an individual the option to defeat the sale violates his or her common law right to a decent burial.

The material in the following section surveys the general legal problems encountered in three general market mechanisms. These mechanisms are: (1) an attempted sale of body parts by a living source; (2) an attempted sale by an individual of his own cadaver parts; and (3) an attempted sale of cadaver parts by survivors entrusted with the right and duty of burial.

a. The Living Source as Seller. The sale of organs from a living source has occasionally been attempted,[127] apparently without

giving rise to criminal prosecution. It is likely, however, that the attempted sale or donation of a vital organ such as a heart would run afoul of state criminal sanctions against suicide.[128] In most states the physician involved in such activity would be guilty of murder, even if he or she acted at the request of the donor source. In addition the buyer might also be liable for soliciting another to commit suicide or murder.

The sale of a non-vital organ by a living source is not specifically prohibited by any state. And in fact, non-vital bodily substances and tissues are routinely extracted and sold. For example, approximately one-half of all of the units of blood collected in the United States are obtained by sale and payment is also routinely made for urine, skin and samples of other bodily fluids. The fact remains, however, that there is the possibility of civil or criminal liability for a physician involved in such procedures. For example, a physician who removes a non-vital organ for sale may be liable for assault and battery, traditionally defined as the unwarranted and unjustifiable infliction of bodily injury or an offensive touching. Consent on the part of the person injured or touched is generally a defense to an assault and battery action but it may be ineffective in the transplant context because the touching to which the source consents is not for his or her medical benefit and indeed may cause serious harm.[129]

Another potential legal barrier to organ sales is the crime of mayhem. Where still enforced this offense may pose problems for the physician who removes the organ. Mayhem is differently defined by state statutes but it typically refers to a willful, malicious, and

permanent disfigurement or disablement of the body accompanied by a breaking of the skin. Some cases have rejected consent as a defense to mayhem but they generally have involved sado-masochistic practices that generally served no useful social purpose. Sale[130] argued that the principles of mayhem should not be extended to organ transplantation because these procedures do have significant social benefit.

b. The Sale of One's Own Cadaver Parts. An individual's right to a decent burial is generally recognized at law. This right, coupled with the right of the public to a sanitary and inoffensive disposition of the dead, is enforced by a common law and in some states, statutory right and duty specified individuals to bury the dead. The right to a decent burial, however, does not entitle the decedent to specify the manner in which he or she is to be buried.[131]

Nevertheless, the deceased preferences may be given great weight as qualifications on the survivors right to bury the corpse in the same way that that right is qualified by the desires of other friends and family. The limited right of the decedent to determine the disposition of his or her remains under this theory is a personal right, not a property right. The disposition is thus not included in the probate estate and the decedent's wishes regarding his or her burial do not carry the legal weight normally attached to testamentary dispositions. The decedent's directions regarding his or her burial normally will be honored in a court but they have been defeated by the strong objections from close relatives, especially from a surviving spouse.[132]

The chairman of the committee that drafted the UAGA noted that it was intended neither to encourage nor to prohibit sales:[133]

> It is possible, of course, that abuses may occur if payment should customarily be demanded; but every payment is not necessarily unethical. On the other hand, drafting a statutory provision to preclude payment will not be easy. Until the matter of payment becomes a problem of some dimensions the matter should be left to the decency of intelligent human beings.

Only the State of Delaware expressly prohibits payment to organ sources. It can be argued that other states would have been more explicit in enacting their versions of the Uniform Act if they had wanted to prohibit organ sales. These states may have felt that the "gift" language of the Act did not extend to sale, but in fact there is no language that would bar sales. If organ sales are neither covered nor expressly prohibited by the Act a source could conceivably make a contract to donate his or her body to a specific individual under the terms of the Act and could receive compensation for making that contract. The alternative to this interpretation is that the common law provisions on cadaver disposition govern and the body simply cannot be sold.

In any event, the ability of the legal system, by itself, to ensure that the market system for organs is not misused is doubtful because many of the problems involved in such a system are not subjects of legal expertise. It seems likely that express legislation detailing the proper operation of a market system would be preferable to ad hoc judicial formulation.

c. Sale by Those Holding the Right to Burial. The right and duty of burial ordinarily belongs to the surviving spouse or next-of-kin, except in those situations in which the spouses have separated or the right is explicitly waived. If the right of burial is not assumed by the spouse, it passes to the next-of-kin in the order of the relation to the decedent unless there is special circumstances of intimacy or close association. The right of burial includes the power to determine the time, manner and place of burial but it is qualified by the interest by the rest of the family and by friends. The right is said to be a trust held for the benefit for all who may have an interest in the remains. Interference with the right of burial by mutilation or withholding of the body is an actionable wrong and the violator may be liable for damages.

If the Act is held not to apply to sales by relatives three aspects of the right to burial may create difficulty for a market system for organs. First, the right to burial has consistently been narrowly construed to encompass only limited discretion as to time, place and manner of burial. It is doubtful that the courts would allow this right to be expanded to enable its possessor to benefit financially, especially in light of the common law maxim that there is no commercial property right in a dead body. Second, the possessor of the right to burial is commonly said to be holding a trust for friends and relatives of the decedent who have an emotional interest in the disposition of the body. If others were to object to the sale of the decedent's cadaver, the sellers' rights as trustee might be successfully defeated. Third, the decedent is entitled to a decent

burial and the attempted sale of his or her cadaver without express statutory authorization may be in violation of that right.

E. SUMMARY

It is apparent that advances in transplant technology are driving the demand for transplantable organs beyond the capacity of the current supply system. Continued reliance on ad hoc pleas and donations, and uncoordinated organ procurement procedures simply does not meet current needs for organs, and surely will not meet the increased demands that are just over the medical horizon. Careful thinking about the source and supply of transplantable organs leads one to consider two separate aspects of the problem -- (1) efforts within the existing framework of the UAGA, and (2) alternatives to reliance on donation.

In theory, the UAGA provides an adequate legal vehicle through which to procure organs for transplantation. A great deal of time, effort, and study went into its preparation in order to ensure that significant legal impediments would be overcome. In practice, however, donations remain an unsatisfactory solution to a pressing problem. There is considerable evidence[134] that important legal provisions of the UAGA are largely ignored by those involved in organ procurement. Although the UAGA explicitly recognizes donor documentation (i.e., a donor card) as sufficient legal evidence of an individual's donative intent (and extends blanket immunity to physicians and other medical personnel "acting in good faith" in regard to organ procurement), the majority of medical institutions do

not permit organ removal without the consent of next-of-kin. While the underlying philosophy of the UAGA is to facilitate the expression of an individual's intent to donate, the reality of the situation is that such intentions are not carried out unless and until a family member or relative consents.

It is apparent that the medical community does not feel that the provisions of the UAGA provide them sufficient legal protection from aggrieved next-of-kin. The important question here whether stronger legal protections are needed to assuage physicians' fears of liability. If so, what guarantees would have to be given to bring their practices into line with the theory of the law regarding organ procurement? It is not at all apparent that additional legal protection is needed to encourage organ donation and procurement under the UAGA. It seems clear that fundamental changes in attitudes must precede any long-term and stable increase in the number of transplantable organs made available through voluntary donation under the UAGA.

We have only recently seen the first of a number of likely legislative solutions to the problem of organ donation and procurement. For instance, as a result of a series of hearings before the Investigations and Oversight Subcommittee of the Science and Technology Committee, Albert Gore, Jr. (D-Tenn) plans to introduce legislation to implement a nationwide strategy to overcome the problems of organ procurement discussed above. The legislation is intended to achieve three primary goals:[135] (1) to increase voluntary donation of organs, (2) to improve coordination of organ

procurement and distribution, and (3) to ensure equitable and timely access to life-saving and medically effective technologies. To meet these goals, the legislation will call for:

(1) formation of a National Center for Human Organ Acquisition;

(2) development of a program to promote organ donation;

(3) development of an aggressive organ acquisition program;[136]

(4) re-establishment of the National Center of Health Care Technology; and

(5) restriction of organ transplantation to designated regional centers.

Because of some degree of skepticism about the ultimate ability of society to provide a sufficient number of organs through donations, several other alternatives to the UAGA have been proposed. We have discussed the legal implications of a number of them here. Any proposal to go beyond voluntary donation, such as compulsory removal, a market system, or "opting out," will inevitably raise complex legal issues that will have to be resolved either legislatively or through the courts. If carefully tailored to avoid infringing on fundamental constitutional rights, none of these alternatives would be inherently illegal.

However, as is the case with reforms or revisions in the UAGA, the important issues do not appear to involve fundamental legal questions. Rather, proponents of any alternative must be prepared to deal with fundamental ethical and moral objections that will surely arise. Such objections may be the expression of deeply held values

and attitudes about the treatment of both the living and the dead (regardless of how those terms are legally, medically, or socially defined), and may only manifest themselves in legal challenges or be cloaked in legal terminology as a means of accomplishing an end. Defending the legal validity of any such alternative is only a relatively minor technical problem, requiring careful legal research and legislative drafting. The more significant undertaking, however, will be to reconcile attitudinal and sociocultural sentiment with the implementation of such proposals.

Section 2 - HEAD V. COLLOTON: PROTECTING THE PRIVACY OF ORGAN AND TISSUE DONORS

A. INTRODUCTION

Patient confidentiality and privacy issues have generated a great deal of discussion in medical, ethical and legal circles in the past decade. Often, discussions center on the tension between society's interest in protecting the confidentiality of medical records and its countervailing interest in allowing use of patient information to promote public health. Seldom, however, are the interests in patient confidentiality directly pitted against the life and health of another human being, for seldom do the physical characteristics and makeup of an anonymous, unrelated individual bear directly upon the life chances of another. However, the resurgent interest in transplantation and the increased need for donor organs and tissues have brought these competing interests into direct confrontation.

Tissue typing information is increasingly stored in medical records as an incident of assessment of individuals as potential organ or tissue donors. Due to advances in electronic data processing, it is now economically and logistically feasible to organize this decentralized tissue information into central "donor information banks", often without having to approach the subject for consent to collect the information.[1] While this type of centralized data collection may be a boon to certain types of transplantation because it allows rapid searches for compatible tissue donors, it also may pose new challenges to our conceptions of confidentiality in

medicine. For example, it is often very difficult to locate compatible bone marrow, platelets and rare types of blood for persons in need of transplants or transfusions. Those needing these services therefore understandably place great value on obtaining information about persons with compatible tissue types. If persons in need of blood, marrow or platelets could gain access to individually identifiable tissue type information, then tissue typed individuals could find themselves exposed to personalized and potentially coercive pleas for donation.

Even if health care providers have a policy of protecting this type of information, unauthorized access could occur in several ways. First, persons could use various types of computer tapping to break into electronically stored tissue type information banks. Second, health care personnel with access to the files could improperly divulge information. Finally, individuals might seek access to centrally stored medical information through legal channels. This article will focus on one such case that has already worked its way through the courts. After a brief discussion of the case, we highlight some of the other ethical and legal aspects of donor confidentiality in the transplantation setting.

B. HEAD V. COLLOTON

The case was brought to court by William Head, a leukemia victim, undergoing chemotherapy at a Texas clinic at the time of the dispute. His prognosis was "grim" in the absence of a bone marrow transplant, a procedure still considered experimental between unrelated persons. A

bone marrow transplant involves removing bone marrow from a healthy person and infusing it into the sick person in the hope that it will generate healthy white blood cells.[2] In Mr. Head's case, only one in approximately 6,000 persons would have blood with the necessary antigen characteristics.[3]

The University of Iowa Hospitals and Clinics include a bone marrow transplant unit, which had formed a bone marrow registry of persons whose blood had been tissue typed by the hospital. Late in 1982, Mr. Head called the transplant unit and, through a series of conversations with a staff member, learned that the hospital's registry included the name of a woman who might prove to be a suitable donor.

The woman was referred to in the court records as "Mrs. X." Her tissue typing was done to determine her suitability as a donor for her three year old son, not for reasons of her own health. The hospital subsequently placed her name in its platelet donor registry. Then, when it later established an experimental program involving bone marrow transplants, it placed her name in the marrow registry, without her knowledge or consent.

When the hospital established the bone marrow transplant program, its institutional review board (IRB) approved a procedure for contacting persons listed in the registry to determine whether they would act as donors. The procedure involved sending a letter to the potential donor informing him or her of the program, its nature and goals, and inviting the individual to participate in it. If the letter was not answered, a staff member was authorized to telephone

the person and ask a series of general questions designed to determine whether the person would volunteer as a donor.

After Mr. Head contacted the bone marrow unit, the unit staff sent Mrs. X the general letter to inform her about the program and to encourage her to participate. When Mrs. X did not respond, a staff member called her and asked her a series of questions, including whether she might ever be interested in being a donor. She replied "Well, if it was for the family, yes. Otherwise, no."

When informed of her decision, Mr. Head asked the hospital try again by telling her that a specific patient might be helped by her donation. Alternately, he suggested that her identify be disclosed to him so that he could contact her directly. The hospital refused, and Mr. Head brought suit.

Mr. Head asked an Iowa trial court to order the hospital[4] to disclose the name and identity of the potential donor either to the court or to his attorney. He proposed that the court or his counsel then be permitted to write the woman and notify her of his specific need for her marrow, and ask her if she would consider being a donor for him.

After hearing the evidence, the trial court ordered the defendants to send Mrs. X the letter.[5] The hospital appealed the decision to the Supreme Court of Iowa, which granted the request for review and held up sending the letter until it could hear arguments presented by both sides.

The legal issues centered on several provisions of the Iowa freedom of information act. Counsel for Mr. Head contended that

information contained in the bone marrow registry--including the identity of Mrs. X-- was a "public record" to which the public has right of access under the Freedom of Information Act.[6] The University of Iowa hospital conceded that the act would classify its bone marrow records as public records because of its status as a state institution. However, the hospital asserted that the information contained in their bone marrow registry was protected under a section of the act that stated that "hospital records and medical records of the condition, diagnosis, care, or treatment of a patient or former patient, including outpatient"[7] are exempt from the public access requirements and in fact must be kept confidential. Counsel for Mr. Head argued that this confidentiality exemption did not apply to the records of persons who submit to tissue typing, rather than diagnostic or treatment measures, because those individuals cannot be considered "patients" and because only the records of patients are exempted from the general disclosure requirements.[8] In response, the hospital argued first that the act protects hospital records regardless of whether they are "patient records". Second, the hospital argued that in any case, a tissue typing record is a "patient record" within the meaning of that term.

As a preliminary axiom, the Iowa Supreme Court stated that the disclosure exemption applied only to the records of current and former patients, including outpatients.[9] As the court stated, the critical issue was therefore "whether Mrs. X was a hospital patient for the purposes of (the act) when she submitted to tissue typing as a potential platelet donor." The court held that she was.

The court noted that the ordinary meaning of the word "patient" is "a person under medical or surgical treatment."[10] However, the court reasoned that the word treatment "is broad enough to embrace all steps in applying medical arts to a person."[11] Moreover, the court noted, this meaning was consistent with case law that recognizes the same duty between physician and donor as exists between physician and patient generally.[12] Perhaps even more importantly, the court stressed that:[13]

> When a person submits to a hospital procedure, the hospital's duty should not depend on whether the procedure is for that person's benefit or the potential benefit of someone else. The fiduciary relationship is the same, and the standard of care is the same. In addition, just as with patients generally, a potential donor has a valuable right of privacy.

Noting that the right of privacy was based in both constitutional[14] and common law,[15] the court stated that the right to avoid publicity, a valuable part of the right of privacy, "can be as important to a potential donor as to a person in ill health."[16] Moreover, it noted the possible chilling effect that disclosure of such information could have upon medical research.[17] The court then concluded that the tissue typing information of Mrs. X was protected by the statutory confidentiality requirement and that it therefore would not allow its release.[18]

C. COMMENTS ON COLLOTON AND CONFIDENTIALITY

While undoubtedly not anticipated when the Iowa freedom of information act was drafted, the major legal issue raised in Colloton

was deceptively simple and straightforward; whether a person who submitted to tissue typing for purposes unrelated to her own medical treatment or diagnosis was a "patient" under the Iowa statute. Yet the very simplicity of the legal question masked the complexity of its ethical and policy implications.

Mr. Head's situation was a compelling one; none would deny the urgency of his appeal, or that Mrs. X might have changed her mind about participating had she been informed that the life of an identifiable individual hung in the balance. In fact, she herself might have benefitted psychologically from the experience. Indeed, it is troubling that Mr. Head was denied a potentially life saving resource, one whose existance was made known to him through the carelessness or lack of awareness of someone in a records office. However, confidentiality in medicine serves several important purposes. First and foremost, it acknowledges and protects the right of the patient to make decisions free from coercion. Second, it rests on the (perhaps naive) conviction that information we volunteer to our health care providers should go no further than the specified recipient, and that personal data will be used for no other purpose than that for which it was divulged. Maintaining confidentiality may be particularly important to the stability of many types of tissue information banks. Many medical ethicists insist that the voluntary participation of individuals in such programs may rest on respect for their privacy, and preservation of the confidentiality of their medical information and identity.

The implications of allowing access to potential donor information are not limited to the facts of this specific case. As pointed out in the hospital's trial briefs, it alone maintains many large potential donor registries other than the one at issue in the Colloton case. The University of Iowa Hospital blood donor registry contains the names of at least 17,000 persons.[19] Blood type information for almost all of these individuals was obtained outside of the context of diagnosis or treatment. If a blood donor registry of this type were open to public scrutiny, then persons in need of relatively rare types of blood could identify and subject persons with compatible blood types to individualized, personal requests that would be undeniably coercive. Those needing blood might also seek the aid of the courts in placing pressure on a potential donor. Such developments would place potential donors in situations of pressure, possible adverse publicity and stress to such an extent that other potential donors would be dissuaded from registering.

In Colloton, however, the highest court of Iowa signalled that the medical records of donors in Iowa public institutions are entitled to the same protection under the law as are records of people we normally think of as "patients." But other questions surrounding the confidentiality of tissue type information remain, questions that raise serious ethical, and in some cases, legal issues.

The background of the Colloton case itself raises several subtle ethical questions. As two expert witnesses at the trial noted, the hospital may have acted in a questionable manner long before its medical records worker discussed the availability of a potential donor

with Mr. Head.[20] Dr. Marc Seigler stated his objections to the hospital's actions in his comments during the trial:[21]

> . . . You have a patient who came in to donate platelets. . . . She was tissue typed because there were people at the University of Iowa Hospital who thought that if one tissue typed platelet donors one could get better platelet survival in recipients of such platelets. I believe that suspicion has been borne out by medical research. (Mrs. X) was then tissue typed and was gone from the university. I mean she was then no longer part of the system.
>
> I again don't know how many years later a computer bank was planned and organized . . . (for a) project I gather was not even thought about when (Mrs. X) . . . was tissue typed. . . . That lady's private, personal information was entered without consent on to this new data bank. That (transfer of information) has absolutely no relationship to the reason for which her tissue type was done in the first place, and that seems to me the first important breach.
>
> Secondly, she was then enrolled as part of the study . . . without ever having consented to be in the bank. . . .
>
> Third . . . (that a) person revealed that there was a match on that bank and went beyond that (and sent out a letter to Mrs. X was) a shocking breach of confidentiality. . . .

Currently, there are few if any legal controls on intra--organizational disclosures of otherwise confidential medical information.[22] Internally conducted searches of a public hospital's patient files and reorganization of this information into data banks within the institution probably would not be affected by the limitations imposed under state freedom of information acts since the limits on disclosure of medical and hospital records apply only to requests by the public rather than to requests by other health and research personnel within the public institution. Given the rapid

adoption of electronic data processing, however, practices such as this will be increasingly commonplace. The question that must be answered is whether we as a society feel that the ease and convenience of allowing nonconsensual use of previously gathered medical information for purposes that do not medically benefit the subject outweigh the infringement on personal privacy and confidentiality interests.

Many other questions relating to confidentiality of tissue type information can--and perhaps will--be litigated in the future. These include:[23]

- The amenability of other state laws, including freedom of information acts to interpretations that would extend medical confidentiality requirements to the records of tissue and organ donors.
- The type and level of sanction that could be applied under existing statutes to institutions who release such information.
- Whether a tissue typed individual whose identity or medical information was disseminated without his or her consent (or the consent of the next-of-kin if the patient is dead or near death) can bring an action against a public or private health care institution or those gaining access to the information to recover monetary damages under legal theories such as breach of contract, invasion of privacy, or negligent infliction of emotional distress.
- Whether hospitals can relay without consent information about the potential donor's identity, medical condition or tissue type to independent organ procurement agencies without running afoul of state statutes controlling access to information contained in medical records.
- What type of information the hospital may legally give to the donee about the donor once a transplant occurs.

. Whether a physician could refuse to release the medical records or identity of a donor where, for example, the recipient of the tissue or organ was bringing a civil action for negligent implantation of a defective organ or tissue.

The uncertain legal status of potential and actual donor information may necessitate enactment or reconsideration of confidentiality guidelines. However, those guidelines, whether implemented by an institution or a legislature must accommodate not only the rights of patients to informational privacy, but also the needs of health care providers for ready access to information necessary for treatment. As one ethicist has noted, "No moral principle can be as simple as 'respect privacy always.' There is a consequentualist tradeoff between protection of privacy and ease of access to needed medical information that is defined by our current state of the art in information processing."[24] Another factor that must be weighed is cost; protection of HLA and other donor-specific information will entail expenditures of both time and money. While we as a society feel that psychiatric records may demand stringent safeguards, it may not be cost effective to protect tissue type information, even though from an ethical standpoint, the patient may be equally entitled to have it protected. The questions we must ask ourselves include: What information should we protect? From whom? At what price? How comprehensive should regulation be? Where do we strike the balance in each case?

At a minimum, persons trained in handling transplant related medical data must be sensitized to the ethical and legal considerations inherent in their work. It may also be advisable for

health care personnel to consider obtaining explicit prior consent from donors to use HLA data for specified purposes. In addition, perhaps the entire data collection and dissemination system should be monitored to correct potential abuses.

We do not have enough information to assess whether Colloton was an anomolous case arising out of an unlikely chain of events; perhaps no similar cases will ever arise. However, this case should provoke discussion and thought about the unique issues of confidentiality that may arise as two rapidly advancing products of the technological era--computerized data processing and tissue transplantation--are increasingly utilized in modern medical practice.

Section 3 - DECLARATION OF DEATH: A SYNOPSIS OF THE PRESIDENT'S COMMISSION REPORT

A. INTRODUCTION

In November of 1978 the United States Congress authorized the creation of a presidential commission with continuing responsibility to study and report on the ethical and legal implications of a number of issues in medicine and research -- the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. The first issue posed in the Commission's congressional mandate was the question of whether law the ought to recognize new means for establishing that human death had occurred. Although apparently straight forward, this question was seen as troublesome for several reasons. First, in many cases, ventilators and other associated medical technologies are capable of maintaining heartbeat and respiration in dead bodies -- those having sustained total and irreversible cessation of all brain functions. Thus, the beating heart no longer plays a central role in differentiating the living from the dead. Second, confusion arose because the same medical technology not only kept heart and lungs functioning in some who had irretrievably lost all brain functions, but also sustained other, less severely injured patients. Inexact medical and legal descriptions of these two categories of cases led to a blurring of the important distinction between patients who were already dead, and those who were simply in the process of dying.

The study of the "ethical and legal implications of the matter of defining death," as it was stated in the congressional mandate, was

also the first report that the President's Commission completed. The study began with hearings and written testimony in May and June of 1980 on the medical, ethical, religious, legal, and public policy aspects of the determination of death. The Commission also sponsored empirical investigations on the various outcomes of respirator support for patients in coma of both tramautic and nontraumatic origin, in order to gain some understanding of how frequently determinations of death by traditional measures of heartbeat and respiration were made more difficult by the medical application of artificial means of life support. The results of this empirical study highlighted the importance of addressing the ethical implications of decisions to cease treatment, since most "heart cases" faced by clinicians involved patients who are failing to recover, not those who had ceased to have any brain functions.

More than 6,000 copies of the Commission Report were distributed throughout the United States and around the world. Copies went to all members of Congress, appropriate offices in the executive branch, state legislatures and administrators in health related positions, members of health professional and law reform organizations, members of the public on the Commission's mailing list, and medical and law school libraries. The volume entitled Defining Death quickly became a standard reference point in the public policy debate on this topic and has been widely cited in the scholarly literature. The material that follows summarizes the major findings from the Commission report.

B. THE NATURE OF THE PROBLEM

As the President's Commission noted, death is the one great certainty. The subject of powerful social and religious rituals and moving portrayals in literature, it has been contemplated by philosophers, probed by biologists, and combatted by physicians. Death, although taboo in some cultures, preoccupies others. In its' report, the President's Commission explored only a small corner of this relatively large topic -- whether the law ought to recognize a new means for establishing that the death of an individual human being has occurred.

Throughout recent medical and legal history, the accepted standard for determining the occurrence of death was the permanent absence of respiration and circulation -- breathing ceased and death was obvious. Questions now arise about continued reliance on the traditional standard because advances in medical technology permit physicians to maintain breathing and heartbeat when the capacity to breath spontaneously has been irretrievably lost.

Such cases present a new category for the law (and for society), to which the application of traditional means for determining death is neither clear nor fully satisfactory. The Commission's mandate was to study and recommend ways in which the traditional legal standards could be updated in order to provide clear and principled guidance for determining whether such individuals are dead or alive.

There are several important reasons why the President's Commission included a discussion of the determination of death in its deliberations. First, consideration of the new approaches to the

determination of death had resulted in attention being paid to underlying questions about the meaning of life and death. Concerns about diagnosing death by measuring the presence or absence of brain function had occasioned the reexamination of the traditional techniques. Consequently, questions were posed about the scientific and clinical bases for the traditional standard for death, and about the understanding of human life upon which that standard rested. Second, other changes in medical abilities had contributed to the concern about the "definition" of death. For example, the importance customarily accorded to a person's beating heart in differentiating the living from the dead was challenged when a "dead" person's heart could beat in the chest of a "living" person whose own heart had not merely stopped, but had been removed from his or her body.

C. OVERVIEW OF THE PRESIDENT'S COMMISSION REPORT

Traditionally, the cessation of heartbeat and of breathing were regarded both by the lay and medical communities as the definitive signs of death. The law, through the judgments of courts in deciding individual cases also articulated this general view. In the frequently quoted words of Black's Law Dictionary, the common law mirrored the physician's definitions of death "as a total stoppage of the circulation of the blood, and a cessation of the animal and vital functions consequent thereon, such as respiration, pulsation, etc."

1. CHAPTER ONE

Developments in medical technology and practice have prompted an examination of the adequacy of the traditional view of the proper

way to determine whether death has occurred. Since respiration is controlled by brain centers, the loss of functions in those centers used to mean that breathing (and consequently heartbeat) would never return. Mechanical respirators and other medical technology now enable physicians to reverse the failure of respiration and circulation in many victims of conditions such as cardiac arrest or trauma. If blood flow to the brain is restored quickly enough (usually within several minutes), these victims may eventually recover unassisted breathing. However, the brain cannot regenerate neural cells to replace the ones that have permanently stopped metabolizing. Hence, longer periods without blood flow (ischemia) or oxygen (anoxia) may cause complete and irreversible loss of all brain functions. When the entire brain has been so severely damaged, spontaneous respiration can never return, even though breathing may be maintained by artificial means for sometime (typically, several days).

2. CHAPTER TWO

Although physicians find themselves unable to rely on respiration and circulation as a means of diagnosing death in artificially maintained, comatose patients, they have developed means of detecting the existence or nonexistence of brain functions and the potential for reversibility in such patients. These tests are intended to measure the organic functioning of the brain, not the mere existence of cellular activity that may continue in some brain cells -- as in cells of other organs, such as the heart and the lungs -- for varying lengths of time after the organ has lost the ability to fulfill any of its functions in an organized manner. In Chapter 2,

the President's Commission concluded that proof of an irreversible absence of function in the entire brain, including the brain stem, provided a highly reliable means of declaring death for respirator maintained individuals.

3. CHAPTER THREE

The diagnosis of death has, of course, significance beyond its role as a physiological concept. The material in Chapter 3 of the President's Commission report examined several different explanations of the "meaning" of human life and human death. Formulations based on the function of the whole brain include those that focus on the integrated functioning of brain, heart and lung, and on the primacy of the brain among organs as the body's regulator. Some people have argued for a "higher brain" formulation, such as one that attempts to enumerate the characteristics essential to "personhood" or one that bases death on the loss of "personal identity," viewed by the President's Commission as a consequence of discontinuity in certain mental processes. Finally, several explanations of death not oriented to brain function were also reviewed, such as those that held death to occur when the soul leaves the body, or that equate life with the flow of air and blood through the body.

4. CHAPTER FOUR

If death were entirely a medical matter, the process of "redefinition" might better be left in the hands of the health professions. However, the standards by which death is determined have significance and consequences that are not limited to medical ones. Accordingly, the standards by which death is to be recognized should

be arrived at publicly, although it will remain for physicians to continue to develop criteria and tests, and to apply them in reaching individual diagnoses.

Traditionally, the law on the determination of death was found in the common law decisions rather than in the statute books. One could, of course, choose to remain in that tradition and await judicial reformulation of the standard of death. Yet this method of law reform has serious drawbacks, among them, delay, uncertainty, and lack of consistency in the rules applicable in different jurisdictions. Consequently, in the past decade half of the states have adopted statutes incorporating the cessation of total brain functions as a ground for declaring death.

Having concluded that such a change should be affected publicly and through legislation, the President's Commission next addressed several basic policy issues. First, how specific -- socially or scientifically -- should such legislation be. After considering the alternatives, from the basic concept of death to the precise clinical procedures for diagnosis, the President's Commission concluded that what would be required would be the promulgation of general physiologic standards for recognizing that death had occurred. Second, a statute ought to meet several additional objectives. Most important, any law should treat similar cases alike and provide consistency among jurisdictions when an issue is as important as determining that a human being has died. As a practical matter, alternative standards may be necessary and appropriate, but

the use of two standards in a statute should not be permitted to obscure the fact that death is a unitary phenomenon.

In the Commssion's view, it was also desirable to limit the change in the law on death to the minimum necessary for the problem at hand, i.e., ambiguity about the status of cases of coma with respirator assistance. Extending the "definition" of death beyond those lacking all brain functions to include, for example, persons who have lost only cognitive functions but are still able to breath spontaneously would radically change the meaning of death. Furthermore, in language as well as content, any legislation ought to make personal sense to lay people and to reflect scientific knowledge and clinical reality.

5. CHAPTER FIVE

Certainty and clarity about the standards for determining death are also matters of concern in the making of public policy throughout the country. Practically, patients are transported across state lines for treatment; if neighboring states had different definitions, confusion would probably result and abuse become possible. State-by-state variation is not justified on a matter that is so fundamental and that rests on biological facts on universal explicability. Accordingly, the President's Commission recommended that all states adopt a uniform statute on determining death to replace existing judicial or statutory formulations. Expecting that uniform law would emerge from this process, the President's Commision concluded that this topic remains an appropriate subject for state rather than federal legislation, except as to those areas where the federal government already exercises jurisdiction.

D. SUMMARY AND CONCLUSIONS OF THE COMMISSION REPORT

As noted above, the enabling legislation for the President's Commission directed it to study "the ethical and legal implications of the matter of defining death, including the advisability of developing a uniform definition of death." In performing its mandate, the Commission reached several central conclusions. These are:

1. That recent developments in medical treatment have necessitated a restatement of the standards traditionally recognized for determining that death has occurred.

2. That such a restatement should preferably be a matter of statutory law.

3. That such a statute should remain a matter for state law, with federal action, at this time being limited to areas under current federal jurisdiction.

4. That the statutory law ought to be uniform among the several states.

5. That the "definition" contained in the statute should address general physiological standards rather than medical criteria and tests, which will change with advances in biomedical knowledge and refinements in medical technique.

6. That death is a unitary phenomenon that can be accurately demonstrated either on the traditional grounds of irreversible cessation of heart and lung functions, or on the basis of irreversible loss of all functions of the entire brain.

7. That any statutory "definition" should be kept separate and distinct from provisions governing the donation of cadaver organs and from any legal rules on decisions to terminate life sustaining treatment.

To embody these conclusions in statutory form the President's Commission worked with three organizations that had already proposed model legislation on the subject, the American Bar Association, The

American Medical Association, and the National Conference of Commissioners on Uniform State Laws. These groups endorsed the following statute, in place of their previous proposals:

> Uniform Determination of Death Act. An individual who has sustained either (1) an irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with acceptable medical standards.

The Commission recommended the adoption of this language in all jurisdictions in the United States.

FOOTNOTES

Section 1

1. Significant advances are being made in immunosuppression. Recent evidence suggests that cyclosporine holds out the promise of reduced risk of rejection.

2. In this section the term "need" is used generically to denote "a lack of something requisite, desirable, or useful." In this sense, need can be thought of as the counterpart of "demand." It should be pointed out, however, that that "need" has several technical meanings in the literature concerned with estimating and projecting health resource requirements. See Evans, Defining the Need for Heart Transplantation, Battelle Human Affairs Research Centers (1982) for a discussion of these issues.

3. Payment sources include grants, private sources, some insurance, and charity.

4. ". . . Cathy Petrace has been on a kidney machine for 5 years. She is only 27, and is close to despair. When she was first put onto haemodialysis she was told it would probably only be for two years until a suitable kidney could be found for transplant, and she might be able to return to something resembling a normal life. Her name stays on the national computer of people waiting for kidney transplants, but no kidney that matches her own has been offered. . . . The kidneys are not available for transplant largely because doctors dealing with likely donors and their relatives don't bother to ask for them." Toynbee, P., in Manchester Guardian, August 15, 1982, p. 5. See also Gunby, Media-Abetted Liver Transplants Raise Questions of "Equity and Decency," 249 Journal of the American Medical Association 1973 (1983).

5. Ad Hoc Task Force on Cardiac Replacement, Cardiac Replacement: Medical, Ethical, Psychological, and Economic Implications. National Heart and Lung Institute (1969).

6. The report concluded the maximum number of replacements per year would be 100 under then prevailing circumstances; 12,000 if immunosuppressive techniques were improved; 22,000 if circulatory assistance devices were available; and 32,000 if inter-species transplants and artifical hearts were available.

7. Artificial Heart Assessment Panel, The Totally Implanted Artificial Heart: Legal, Social, Ethical, Medical, Economic, and Psychological Implications. National Heart and Lung Institute (1973).

8. Schroeder, Current Status of Cardiac Transplantation, 1978, 241 Journal of the American Medical Association 2069 (1978).

9. Based on the assumption that one of four individuals younger than 50 years of age dying of cardiac disease would be a candidate for transplantation.

10. Pennock et al., Cardiac Transplantation in Perspective: Survival,Complications, Rehabilitation, and Cost, 83 Journal of Thoracic and Cardiovascular Surgery 168 (1982).

11. Katz and Proctor, Social-Psychological Characteristics of Patients Receiving Hemodialysis Treatment for Chronic Renal Failure: Report of a Questionnaire Survey of Dialysis Centers and Patients During 1967. U.S. Department of Health, Education and Welfare (1969); Katz, Patients in Chronic Hemodialysis in the United States--A Preliminary Survey, 3 Social Science and Medicine 669 (1970)

12. P. L. 93-603.

13. The legislation provided benefits to all ESRD patients who were not federal employees or recipients of Veterans Administration benefits. The ESRD benefit covered 80% of the covered cost, the remainder to be paid by the patient or a third party.

14. Crystal, The Federal Position on Self-Dialysis, 6 Dialysis and Transplantation 49 (1977).

15. Data from the Health Care Financing Administration. This figure is reported in Evans, Blagg and Bryan, Implications for Health Care Policy: A Social and Demographic Profile of Hemodialysis Patients in the United States, 245 Journal of the American Medical Association 487 (1981).

16. Health Care Financing Administration, 1981 End-Stage Renal Disease: Annual Report to Congress, U.S. Government Printing Office (1981). It is interesting to note that transplant patients represented 8.2% of the ESRD population in 1980, a net decrease of 0.2% over 1979.

17. We do not address the issue of demand for other medical resources needed to establish and maintain a heart transplantation program within a medical facility, i.e., surgical teams and logistics necessary to support it. The focus here is on the supply of and demand for hearts for transplantation.

18. Evans, Health Care Technology and the Inevitability of Resource Allocation and Rationing Decisions: Part I, 249 Journal of the American Medical Association 2047 (1983), Part II, 249 Journal of the American Medical Association 2208 (1983).

19. Evans, supra, citing Cooper, Rationing Health Care (1977); Katz and Capron, Catastrophic Diseases: Who Decides What? (1975).

20. Weinstein and Stason, Foundations of Cost Effectiveness Analysis for Health and Medical Practices, 296 New England Journal of Medicine 716 (1977).

21. For general discussions of these issues, see Mechanic, The Growth of Medical Technology and Bureaucracy: Implications for Medical Care, 55 Milbank Memorial Fund Quarterly 61 (1977); Mechanic, Medical Sociology 2nd Ed., (1978); Childress, Rationing of Medical Treatment. In Reich, Encyclopedia of Biomedical Ethics, (1979).

    Others have used the terms "microallocation" and "macroallocation" to refer to rationing and allocation as they are used here. Blumstein, Constitutional and Legal Constraints on the Rationing of Medical Resources. The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1982).

22. The latest analysis of informed consent in the health care setting is in Making Health Care Decisions: A Report on the Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship, Volume One: Report. President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (1982).

23. See Curran, A Problem of Consent: Kidney Transplantation in Minors, 34 New York University Law Review 981 (1959).

24. As we discuss later, there still is little assurance that one's wishes will be carried out if next-of-kin do not consent or cannot be found in time to provide consent.

25. "The Church took the body to itself. It held that a corpse was appropriated by it, by divine service and consecrated burial. . . ." Jackson, The Law of Cadavers, 2nd Ed., p. 126, 1950. The ecclesiastical courts in England had jurisdiction over all controversies involving the burial of corpses, including the place and type of burial. The courts of common law (the secular courts) upheld the right of everyone, except felons, heretics, and suicides, to be buried in the churchyard, but they did not have control over the body or its disposition. This separation or jurisdiction led to anomolous results--while it was larceny to take a person's coffin or to remove clothing from a corpse, it was not a felony to steal the corpse itself. Note, The Sale of Human Body Parts, 72 Michigan Law Review 1182, 1242 (1974), hereinafter referred to as Sale.

26. Coke, E. Institutes, 1973, 3, 203, cited in Sale, at 1242.

27. This proposition, and Coke's rationale for it have been subject to considerable scholarly criticism, both as to its linguistic and legal accuracy. At this point in history, such debates are probably irrelevant, because the doctrine served to legitimate what was and continues to be a widely held social perception of the appropriate handling of dead bodies.

28. In re Beekman Street (N.Y. Sup. Ct. 1856), Report of Referee Samuel B. Ruggles, cited in Sale. In order to widen a street, the city of New York condemned part of a cemetary in which the body of Moses Sherman had lain for more than 50 years. His daughter filed suit to claim compensation for the disturbance of her father's remains.

29. In re Beekman Street (N.Y. Sup. Ct. 1856) at 519.

30. Douglas v. Stokes, 149 Ky. 506, 149 S.W. 849 (1912). The next-of-kin were said to have a "property right" in the body. The right could not be conveyed (through sale or gift) and could only be exercised for the purpose of burying the body. The right not only had no monetary value, but was the source of a financial obligation on the part of the next-of-kin to assume the costs of the burial.

31. Reniham v. Wright, 126 Ind. 536, 25 N.E. 822 (1890).

32. Donnell v. Sloak, 123 Cal. 285, 55 P. 906 (1899); Southern Life and Health Insurance Company v. Morgan, 21 Ala. App. 5, 105 S. 161, cert. denied, 213 Ala. 413, 105 S. 168 (1925); Teasley v. Thompson, 204 Ark. 959, 165 S.W.2d 940 (1942).

33. Although it may be that there are no property rights in a corpse, one can rest assured that University College in the University of London has a legal interest (that it would defend to the death) in the preserved corpse of Jeremy Bentham, which is brought out to sit at a table each year at the Annual Dinner of the Bentham Club.

34. Sadler and Sadler, Transplantation and the Law: The Need for Organized Sensitivity, 57 Georgetown Law Journal 5 (1968).

35. The earliest reported case addressing this issue actually occurred in 1938, In re Johnson's Estate, 169 Misc. 215, N.Y. S.2nd 81 (1938). The deceased had left a codicil to her will in which she directed that her body be donated for medical research. The New York Surrogate Court overruled earlier American decisions that had held that there were no property rights in a dead body and upheld the bequest. The case is of limited value as a precedent because a New York statute expressly granted the right to dispose of one's own body through the provisions of a will. More important, however, is the fact that no next-of-kin contested the donation of the body.

36. 105 N.H. 290, 198 A.2nd 654 (1964).

37. Both medical schools declined to accept the gift of Metalious' body.

38. The decision is less than satisfactory from an analytical point of view. In the first place, it is unclear how the court determined that "donation" was the primary purpose and "no funeral" the secondary purpose of Metalious' intentions. In the second place, the two aspects of the will are easily separable. Failure of the attempted donation simply does not negate the intention to have no funeral services. In reading the court's opinion, one senses the lack of enthusiasm the court had for effectuating the intentions of the will. Faced with a living and breathing spouse who wished to provide a remembrance for his wife, the court paid lip service to her intentions and struggled for a legal construct with which to defeat them.

39. It is not clear what the court's decision would have been had the gift to a medical school been accepted. The court specifically noted that the case did not involve the question of the validity of a will provision for the donation of a body for research or medical training.

40. The degree to which times have indeed changed is illustrated by the press coverage given Henry Fonda's donation of his corneas upon his death. The only publicity that his action received were several minor references in the media. As yet, the unnamed recipient of his corneas has not appeared to tell what it is like to see the world through Tom Joad's eyes.

41. Comment, The Law of Dead Bodies--Impeding Medical Progress, 19 Ohio State Law Journal 455 (1958); Note, The Law of Testamentary Disposition--A Legal Barrier to Medical Advance, 30 Temple Law Quarterly 40 (1956); Note, Donation of Dead Bodies and Parts Thereof for Medical Use, 21 University of Pittsburgh Law Review 21 (1960).

42. Louisell, The Procurement of Organs for Transplantation, 64 Northwestern University Law Review 607 (1970).; Richards, Medical-Legal Problems of Organ Transplantation, 21 Hastings Law Journal 77 (1969); Sideman & Rosenfeld, Legal Aspects of Tissue Donation from Cadavers, 21 Syracuse Law Review 825 (1970); Stason, The Uniform Anatomical Gift Act, 23 Business Law 919 (1968); Note, The Sale of Human Body Parts, 72 Michigan Law Review 1182 (1974).

43. Handbook of the National Conference of Commissioners on Uniform State Laws, 111 (1965).

44. The model was entitled the Uniform Anatomical Gift Act, and was promptly endorsed by the American Bar Association and the Medical-Legal Liaison Committee of the American Medical Association.

45. Uniform Act, §2. Reference to Uniform Act provisions hereinafter refer to 15 Real Property, Probate and Trust Journal 825 (1980).

46. Section 2(a).

47. Section 1(e) defines "part" to mean organs, tissues, eyes, bones, arteries, blood, other fluids, and any other portions of a human body.

48. Section 3.

49. Section 4(a).

50. Section 4(b). This document may, but need not, be a donor card.

51. Section 4(b).

52. Section 2(b); Section 4(e).

53. Section 2(c).

54. Section 4(b).

55. Section 6(a)(1).

56. Section 6(a)(2). A gift may also be amended or revoked by a statement made to an attending physician during a terminal illness or injury (Section 6(a)(2)), or by a signed document found on the donor's person or in his or her effects after death (Section 6(a)(4)).

57. Section 6(b). Section 6(c) also provides that anatomical gifts made in a will may be revoked or amended in the manner provided in state law for the amendment or revocation of wills or will provisions in general.

58. Section 4(c). Some states have included chiropractic colleges as permissible recipients. See, Minnesota Statutes Annotated, §525.923.

59. Section 4(c).

60. Section 7(a).

61. Section 4(d).

62. Section 4(d).

63. Section 4(c).

64. Section 7(b) 20.

65. Section 7(a).

66. The notes accompanying the Uniform Act explain that "the entire Section 7 merits genuinely liberal interpretation . . . to encourage and facilitate the important and ever increasing need for human tissue and organs. . . ."

67. Best, Transfers of Bodies and Body Parts under the Uniform Anatomical Gift Act, 15 Real Property, Probate and Trust Journal 807 (1980), Comment to Section 7, p. 835.

68. See President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Defining Death: A Report on the Medical Legal and Ethical Issues in the Determination of Death (1981).

69. Stason, The Uniform Anatomical Gift Act, 23 Business Lawyer 919, 928 (1968).

70. See Section 504 of the Rehabilitation Act of 1973, 29 U.S.C. Section 794 (1978); Title VI of the Civil Rights Act of 1964, 42 U.S.C. §§2000(a)-2000(d)(4) (1970); Merrikin and Overcast, Fundamental Legal Rights and Governmental Regulation of Heart Transplantation, Battelle Human Affairs Research Centers (1983).

71. Weissman, Why the Uniform Anatomical Gift Act has Failed? 116 Trusts and Estates 264 (1977); Kolata, Organ Shortage Clouds New Transplant Era, 221 Science 32 (1983); Gunby, Panel Ponders Organ Procurement Problem, 250 Journal of the American Medical Association 455 (1983); Iglehart, Transplantation: The Problem of Limited Resources, 309 New England Journal of Medicine 123 (1983).

72. The British experience with donations has been similarly unremarkable. The British Ministry of Health noted that the:

> (E)experience with the eye-donor campaigns, which had been run by the Royal National Institute for the Blind since 1961, suggested that it would not be possible, however, vigorous the campaign, to enroll a sufficiently large proportion of the population to yield an adequate supply of organs for transplantation. New York Times, January 17, 1968. Section A, at 18, Column 3.

73. Dukeminier & Sanders, Organ Transplantation: A Proposal for Routine Salvaging of Cadaver Organs, 279 New England Journal of Medicine 413 (1968).

74. Id. at 415.

75. Freud, Our Attitude Towards Death, 4 Collected Papers 304 (1925).

76. Overcast, Evans, Bowen, Hoe, and Livak, Problems in the Identification of Potential Organ Donors: Misconceptions and Fallacies Associated with Donor Cards, Journal of the American Medical Association, in press.

77. van der Vliet and Koostra, The Transplant Coordinator: An Answer to the Shortage of Cadaveric Kidney Donors, 34 Netherlands Journal of Medicine 1 (1982); van der Vliet, Koostra, and Krom, Cadaveric Organ Retrieval for Transplantation, 6 World Journal of Surgery 478 (1983).

78. Bart, Macon, Whittier, Baldwin, and Blount, Cadaveric Kidneys for Transplantation: A Paradox of Shortage in the Face of Plenty, 31 Transplantation Proceedings 379 (1981); Bart, Macon, Whittier, Baldwin, and Blaunt, Increasing the Supply of Cadaveric Kidneys for Transplantation, 1981 Transplantation 383 (1981).

79. Sells, Let's Not Opt Out: Kidney Donation and Transplantation, 5 Journal of Medical Ethics 165 (1979); Fletcher, Cardiac Transplantation and the Artificial Heart: Ethical Considerations, Circulation (in press).

80. The National Heart Transplantation Study will conduct a new survey of potential organ donors. See The Potential Organ Donor Survey, Battelle Human Affairs Research Centers (1982).

81. Dukeminier, Supplying Organs for Transplantation, 68 Michigan Law Review 811, 830 (1970).

82. Haney, Issues and Considerations in Requesting an Anatomical Gift, 1 Social Science & Medicine 635 (1973); Dukeminier, Supplying Organs for Transplantation, 68 Michigan Law Review, 811, 831 (1970). Leslie, Obtaining Consent for Organ Donation, The International Association of Tissue Banks, Inc., (1983).

83. The data indicate, however, that patients generally demonstrate a high capacity for handling such information in an open manner or are able to use defense mechanisms to protect themselves from pyschological harm. It is also argued that more harm results when the patient deliberately is not told his or her fate. Brim, Freedman, Levine and Scotch (Eds.), The Dying Patient (1970).

84. Haney, Issues and Considerations in Requesting an Anatomical Gift, 1 Social Science & Medicine 635 (1973).

85. Simmons and Simmons, Organ Transplantation: A Social Problem, 19 Social Problems (1971). See Overcast, Evans, Bowen, Hoe, and Livak, Problems in the Identification of Potential Organ Donors: Misconceptions and Fallacies Associated with Donor Cards, Journal of American Medical Association, in press.

86. If long-term storage or holding of organs was possible, many of these problems would disappear. In the meantime, however, donated organs and recipients must be matched very quickly. This need for speed results in at least two undesirable side-effects of transplantation. First, a surgeon may have to implant an organ with less than desirable tissue matching, simply because that is the only organ available and the choice is between it and death. Second, many useable organs may go to waste because there are not suitable recipients.

87. Freidson, The Organization of Medical Practice. In Freedman, Levine, and Reeder (Eds.), Handbook of Medical Sociology (1963).

88. See Leslie, Obtaining Consent for Organ Donation, The International Associations of Tissue Banks (1983). Haney suggests that the form and trajectory of a patient's death will influence the possibility of obtaining an anatomical gift. He divides the process of dying into four categories:

    1) unexpected death. This category is one of the most disturbing forms of death due to the shock it inflicts and the lack of time it allows for preparation. Under present circumstances, it is a very limited source of donor organs because procedures to maintain the viability of organs are not routinely undertaken. By the time consent is obtained, the organs may no longer be useful. Thus, while deaths in emergency rooms are often the best potential source of donor organs, they often are not utilized.

    2) expected quick death. Here time pressures are also important, and the problems are compounded by the necessity of involving the family in the decisionmaking process.

    3) expected to die, but not quickly. This situation may be complicated by the presence of anticipatory grief, and the probability of obtaining an anatomical gift is a function of the family's trust and positive sentiment toward the doctor which remains after death becomes a certainty.

    4) slow death. The main property of this form of dying is unpredictability, both biological and psychological. The family may become so involved in playing out the death scene as a gentle passing into sleep that any request for an organ donation may be seen as disruptive. Haney, Issues and Considerations in Requesting an Anatomical Gift, 1 Social Science & Medicine 635 (1973).

The discussions and recommendations of a recent Surgeon General's Workshop were permeated with references to beliefs, values, attitudes, and perceptions as barriers to donation of solid organs for children. The title of the workshop itself is instructive. See Surgeon General's Workshop on Solid Organ Procurement for Transplantation: Educating the Physician and the Public, Suggestions for the Surgeon General from the Discussion Groups, June 1983.

89. Knutson, Cultural Beliefs on Life and Death. In Brim, Freedman, Levine and Scotch (Eds.), The Dying Patient (1970).

90. This is not so much the purpose of the Uniform Act as it is other laws (such as autopsy, and medical examiner and coroner statutes) that compete for control and utilization of the dead body.

91. The ethical aspects of opting-out are briefly discussed in Fletcher, Cardiac Transplantation and the Artificial Heart: Ethical Considerations, Circulation, in press.

92. Weissman, Why the Uniform Anatomical Gift Act has Failed, April Trusts & Estates 264 (1977). The following discussion draws heavily on Weissman's analysis.

93. Section 7.

94. The Uniform Act, however, contains no provisions for protecting the individual from coercive demands to make an anatomical gift. See Groll & Kerwin, The Uniform Anatomical Gift Act: Is the Right to Decent Burial Obsolete? 2 Loyola University Law Journal 274 (1971).

95. Ischemia refers to the lack of blood flow to a tissue or organ. In the transplantation context it means the time between the removal of an organ from a donor and its implantation in a recipient. As a general rule, the longer the ischemic time, the lower the probability of successful transplantation of an organ. The upper limit of ischemic time for a transplantable heart is approximately 4 hours.

96. Weissman presents a very limited discussion of the origin and development of this right. See note 86, at p. 281.

97. Note, Compulsory Removal of Cadaver Organs, 69 Columbia Law Review 693 (1969).

98. Note, A Braunfeld v. Brown Test for Indirect Burdens on the Free Exercise of Religion, 48 Minnesota Law Review 1165 (1964).

99. Reynolds v. United States, 98 U.S. 145 (1978).

100. 125 N.W.2d 588 (1963).

101. 366 U.S. 599 (1961).

102. Id.

103. Welsh v. United States, 398 U.S. 333 (1970).

104. Olmstead v. United States, 277 U.S. 438 (1928).

105. Application of the President and Directors of Georgetown College, Inc., 331 F.2d 1000 (1964).

106. The requirements of the Fifth Amendment have been imposed on the states through the Due Process clause of the Fourteenth Amendment. Chicago, Burlington & Quincy Railroad v. Chicago, 166 U.S. 226 (1897).

107. See Mugler v. Kansas, 123 U.S. 623 (1887).

108. See Pennsylvania Coal v. Mahon, 260 U.S. 393 (1922).

109. Michelman, Property, Utility, and Fairness: Comments on the Ethical Foundations of "Just Compensation" Law, 80 Harvard Law Review 1165, 1184-85 (1967).

110. United States v. Grand River Dam Authority, 363 U.S. 229 (1960); United States v. Willow River Power Company, 324 U.S. 499 (1945).

111. Larson v. Chase, 47 Minn. 307, 50 N.W. 238 (1891).

112. Parker v. Quinn-McGowen Co., 262 N.C. 560, 138 S.E.2d 214 (1964).

113. Gostowski v. Roman Catholic Church, 262 N.Y. 320, 186 N.E. 798 (1933); Barela v. Frank A. Hubell Co., 67 N.M. 319, 355 P.2d 133 (1960).

114. Palmquist v. Standard Accident Insurance Co., 3 F. Supp. 358 (S.D. Cal. 1933).

115. See Parker v. Quinn-McGowen Co., supra.

116. Pettigrew v. Pettigrew, 207 Pa. 313, 56 A. 878 (1904); Larson v. Chase, supra.

117. Berman v. Parker, 348 U.S. 26 (1954).

118. See Clark v. Nash, 198 U.S. 361 (1905).

119. If several states were to enact compulsory removal statutes, it is likely that organs would be exchanged among them in order to maximize tissue-matching between organs and recipients.

120. The material in this section relies heavily on the detailed presentations in Dukeminier, Supplying Organs for Transplantation, 68 Michigan Law Review 811 (1970); and Note, The Sale of Human Body Parts, 72 Michigan Law Review 1182 (1974).

121. Note, The Sale of Human Body Parts, 72 Michigan Law Review 1182, 1217 (1974).

122. Sale at p. 1217.

123. Sale at p. 1217.

124. R. Titmuss, The Gift Relationship, at p. 102. Titmuss reports that a survey of paid blood donors has shown that a disproportionately high proportion of blood donors were drawn from the lower socio-economic groups. In addition, it has been shown that blacks donate far fewer kidneys than whites. At one transplant center, only 25% of kidney transplants involved living related black donors, and 41 of 47 cadaver organs were donated by nonblacks. Tentative reasons for this finding were: (1) lack of knowledge about transplantation, (2) disassociation and lack of communication between blacks and the medical community, (3) religious fears, (4) fears of premature death, and (5) perceptions of racism. See Callender, Bayton, Yeager, and Clark, Attitudes Among Blacks Toward Donating Kidneys for Transplantation: A Pilot Project, 74 Journal of the American Medical Association 807 (1982).

125. Titmuss, supra at p. 245-246.

126. At. p. 1218.

127. Dukeminier, Supplying Organs for Transplantation, 68 Michigan Law Review 811, 825 (1970).

128. Note, Criminal Law -- Attempted Suicide, 40 North Carolina Law Review 323, 326 (1962).

129. Sale, at pp. 1238-1239.

130. At p. 1240.

131. Sale at p. 1247.

132. The Uniform Anatomical Gift Act adds nothing to clarifying the situation with regard to the sale of organs because the Act is phrased entirely in terms of gifts.

133. Sale at p. 1248.

134. Overcast, Evans et al., Problems in the Identification of Potential Organ Donors: Misconceptions and Fallacies Associated with Donor Cards. Submitted to Journal of the American Medical Association.

135. Testimony of the Honorable Albert Gore, Jr., before the Subcommittee on Health and the Environment, Committee on Energy and Commerce, July 29, 1983.

136. If voluntary efforts are not successful, the legislation allows consideration of the following:

(1) provisions of incentives, such as a voucher system or tax credits for donor estates;

(2) a system of mandated choice, such as requiring selection donor status (yes/no) at the time of driver's license insurance; and

(3) adoption of a system of presumed consent, unless objection is registered in advance.

See Appendix 32-A

Section 2

1. Computer assisted textual search and data processing techniques now allow health care personnel to retrieve meaningful data from a large bank of otherwise unorganized information and also create profiles of large groups of people with greater ease and at less expense than ever before. For a review of some of the legal implications of electronic data processing in health care, see, Note, Electronic Data Processing in Private Hospitals: Patient Privacy, Confidentiality and Control, XIII Suffolk University Law Review 1386, 1397 (1979).

2. Storb, R. Human bone marrow transplantation. Transplant Proc. 15:1379-1384, 1983. Thomas, E.D., Buckner, C.D., Clift, R.A. et al. Marrow transplantation for acute nonlymphoblastic leukemia in first remission. N Engl J Med, 301:597, 1979. Thomas E.D., Storb, R., Clift, R.A., et al. Bone marrow transplantation. N Engl J Med, 292:832, 1975.

3. Head v. Colloton, 331 N.W. 2d 870, 872 (Iowa 1983).

4. While the named defendants in this case were actually the two hospital employees identified earlier, for purposes of clarity and convenience, the hospital is here referred to as if it were the named defendant.

5. 331 N.W. 2d at 873.

6. Code of Iowa, Ch. 68A (1971).

7. Section 68A.7(2). The hospital also asserted that section 68A.8 applied. It provides that the holder of public records prohibit disclosure when a court finds that "such examination would substantially and irreparably injure any person or persons."

8. In making their assertions, both plaintiff and defendants relied on language in the case of Howard v. Des Moines Register and Tribune Co, 483 N.W. 2d 289 (Iowa 1979), cert. denied, 445 U.S. 904 (1980). In Howard, a plurality of the court held that documents in the working files of the Iowa Governor's office were not confidential under section 68A.7(2) even though they contained information about the sterilization of a nursing home patient. The opinion stated:

Section 68.A.7(2), which exempts "hospital records" and "medical records" of a "patient or former patient, including outpatient," does not apply because the documents here were neither compiled for diagnostic or treatment purposes by hospital or medical personnel nor maintained as records of a hospital or physician.

Counsel for Mr. Head argued that Howard made it clear that a hospital record would not be considered confidential under the Act unless it was a record of patient diagnosis and treatment. The defendants argued that the opinion showed that the modifying language relating to patient care and treatment applied only to the term "medical record." They asserted that all hospital records are confidential, whether they are patient records or not.

9. 331 N.W. 2d at 874.

10. Id. at 875 (citations omitted).

11. Id.

12. Id. at 876, citing Fleming v. Michigan Mutual Liability Co., 363 F.2d 186 (5th Cir. 1966); Bonner v. Moran, 75 App. D.C. 156, 126 F.2d 121 .

APPENDIX 33-A

PROPOSAL FOR ORGAN REMOVAL IN THE ABSENCE OF OBJECTION

PROPOSAL FOR ORGAN REMOVAL IN THE ABSENCE OF OBJECTION

Section 1

Whenever there exists a shortage of any anatomical parts of cadavers, which parts are needed for either therapy or transplantation to any living person, any authorized person may remove such parts and perform any examination necessary to assure the medical acceptability of the part for such purposes, provided, that person does not have actual notice of a proper objection to such removal.

Section 2

The removal of such part or parts shall be done in such a manner as to cause no unnecessary interference with embalming and the use of the body in funeral services. The authorized person shall cause the part or parts to be removed with unnecessary mutilation .

Section 3

The physician who certified death shall not participate in the procedures for removing or transplanting any part of such cadaver.

Section 4

The following are authorized persons: any surgeon, physician or other persons licensed by the state to remove such part or parts.

Section 5

Any part removed from a cadaver may be placed in a bank or storage facility licensed, accredited or approved under the laws of any state for storage of human body parts.

Section 6

No authorized person may act pursuant to this chapter unless the identity of the cadaver is known and the Central State Anatomical Objection depository is checked for objections to the removal of any part or parts of the body.

Section 7

Prior to death any person may object, either in a writing signed by such person or orally before two witnesses, to the removal of any part of parts of his body after death. Such objections may be filed by mailing to the Central State Anatomical Objection depository. Objections may be revoked in the same manner in which they may be made. However, revocation of an objection filed with Central State Anatomical Objection depository shall be in writing signed by such person and shall not take effect until 30 days after receipt thereof.

Section 8

Any of the following persons, in order of priority stated, when persons in prior classes are not available at the time of death, and in the absence of actual notice of contrary indications by the decedent or actual notice of opposition by a member of a prior class, may object to the removal of any part or parts of the decendents body:

(1) the spouse

(2) an adult son or daughter

(3) either parent

(4) an adult brother or siste

(5) a guardian of the person of the decedent at the time of his death

(6) any other person authorized or under obligation to dispose of the body.

Any objection by a person designated above (1-6) shall be made by a document signed by him, or made by his telegraphic, recorded telephonic or other recorded message.

Section 9

No authorized person who acts without negligence pursuant to this chapter in the good faith believe that such anatomical parts are in short supply and will be used either for transplantation or therapy shall be liable for damages in any civil actin or subject to prosecution for his acts in any criminal proceeding.

The provisions of this Act are subject to the laws of this state prescribing powers and duties with respect to autopsies.

NOTE: The Proposal contemplates the creation of a Central State Anatomical Objection depository which physicians could reach by telephone twenty-four hours a day. If adopted by several states there would be a National Objection Depository.

CHAPTER 34

LEGAL ISSUES SURROUNDING PROVIDERS

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Section 1 - DUE PROCESS AND EQUAL PROTECTION CONSIDERATIONS IN HEART TRANSPLANTATIONS

A. INTRODUCTION

In the last two decades, a dramatic change has occurred in medical care. While in times past, major developments in medicine were primarily associated with advances in control of infections and infectious diseases, today technology has come to dominate our perceptions of medical innovation.[1] This change in emphasis has been accompanied by the unchecked diffusion of many new diagnostic and treatment modalities[2] without the simultaneous weighing of their costs and benefits.[3] Many critics therefore have called for a halt to indiscriminate increases in government health care expenditures, and for externally imposed changes in medicine's incentive structure and our laissez-faire posture toward medical technology diffusion.[4]

Because of its high visibility and high cost, heart transplantation has become a focal point of such policy debates; as transplant techniques advance[5] and heart transplantation becomes more widely available, vital policy issues will inevitably be raised--issues that will become more critical as the procedure gains increasing public recognition as a possible (if not affordable or obtainable) treatment for a life-threatening condition. One of the most pressing issues will be the extent to which the federal government should underwrite the costs associated with heart transplantation, and the corresponding fiscal implications such undertakings will have for the already overburdened Medicare system.[6] While reimbursement issues have the greatest immediacy, the diffusion of innovative, yet costly

Biotechnological procedures such as heart transplantation raises additional public concerns. Chief among them are: (1) public exposure to unsafe or inefficacious medical procedures or practices; (2) inefficient use of scarce medical resources; (3) escalating costs associated with hospital care in general; and (4) the equity concerns that may arise if certain medical treatments, developed with the assistance of public monies, can be made available only to a few because of physical or financial resource scarcity.

These concerns may lead the government to play an increasingly active and important role in controlling the diffusion of these new technologies. Despite the current emphasis on market-oriented rather than regulatory solutions, another impetus to governmentally sponsored reform may be provider and insurer reluctance to engage in cooperative activities aimed at reducing duplication of services because of fear of antitrust liability.[7]

If the government does decide to act, its role could assume many forms. Medical procedures or professionals could be directly regulated by state or federal law, indirectly regulated via conditions imposed on receipt of federal monies, or informally regulated by government coverage decisions.

The mechanism with the fewest aspects of formal regulation is coverage policymaking for government-financed health programs. Because its most immediate concern is with controlling the costs associated with such programs, the federal government may refuse to reimburse or may limit the amount of reimbursement for particular medical services and procedures that it finds to be insufficiently

cost effective. While such coverage decisions may not be attempts to regulate the actual performance of procedures, the monetary incentives or disincentives they create may have a powerful effect on the patient's ability or willingness to undergo expensive forms of treatment, and may also affect the ability of the transplant center to choose patients free of financial considerations. Coverage policies, thus may have a strong impact on decisions to open or close transplant facilities or to expand or constrict services, which in turn will affect the availability of non-reimbursed care.

Increasing concern over hospital cost containment, limited resources, safety, efficiency, and equity of access may lead the government beyond simple coverage limitations to more formal restrictions via conditioning the receipt of federal monies, or direct state or federal statutory or administrative regulation. If the government choses to act by conditioning receipt of federal monies, the scope of the condition could be limited to activities affecting reimbursed care only or broadened to apply to all transplant activity, reimbursed or not. Thus, the Health Care Finance Administration could choose to limit Medicare reimbursement for heart transplantation to centers of physicians who meet certain qualitative standards.[8] Alternatively, it could condition receipt of a variety of federal monies on imposition of qualitative standards on all transplant activity undertaken by the provider or facility. Through similar mechanisms, the government could require utilization of strict patient selection criteria, either for potential Medicare beneficiaries alone or for all transplant candidates. Rather than impose qualitative

standards or patient selection criteria, the government could place an absolute limit on the number of centers or surgeons who could be reimbursed for transplant services,[9] or more drastically, use the funding power to secure compliance with a permit system that would limit the number of centers or surgeons who could engage in transplant activity at all. Such mechanisms could also be used to establish regional transplant facilities.

The federal government could also seek to impose conditions on the states rather than on the health care provider. It could, for example, require the states to enact facility or health care professional licensure laws as a condition of receiving federal funds. This form of regulation of state activity is exemplified by a federal statute that conditions state receipt of federal health care funds on state enactment of certificate of need laws.[10]

The state or federal governments could also regulate directly through enactment of statutes that would apply regardless of status as a recipient of financial assistance. Thus, they could seek to impose across the board certification or licensure requirements or limit transplant activities to designated regional transplant centers. At the farthest end of the regulatory spectrum, the government could seek to prohibit the performance of procedures such as heart transplantation altogether. While the probability of the adoption of this last alternative is extremely remote, it has been discussed by several commentators as a means of achieving equity of access to scarce medical procedures.[11]

Thus, a wide range of policy options exist for reimbursement and regulation of high cost, biotechnologically oriented medical procedures such as heart transplantation. At one end of the spectrum, the federal government could seek to affect diffusion of procedures such as heart transplantation through simple coverage decisions alone. At the other, it could seek to prohibit or restrict severely the use of such procedures by statute. But it or the states could also choose any of a number of intermediate approaches, as discussed above. Yet before any action along these lines can be taken, constitutional concerns about the legitimacy of the options will have to be addressed. For example, would government limitations or conditions on federal health care reimbursement unconstitutionally infringe on a person's rights by reducing his or her ability to effectuate a decision to undergo a particular form of treatment? Would all forms of government regulation of the availability or utilization of a procedure be constitutionally permissible?

Given the likelihood that the public increasingly will demand access to heart transplantation and other life saving biotechnological innovations, these and related questions assume immediate import. Even if the law is not yet fully developed on these points, it is likely that the public, medical professionals and other members of the health care industry will press for legal clarification of these issues. The purpose of this section, then, is to respond to these concerns and help focus future debates on this topic.

Throughout the recent history of health care in the United States, the major issues of political concern have been the improved

quality of, and increased access to medical care. Government support for health care research grew at a rapid rate, and technological progress improved the quality of medical care in many areas. Programs such as Medicare and Medicaid provided financial assistance for the delivery of health care services to a number of identifiable populations within the country. In addition to health care delivery programs, however, attention came to be focused on new and emerging medical technologies, such as kidney dialysis and organ transplantation.

Progress in improving the quality and availability of health care services, led to a more recent concern over broader health policy issues, such as the overall cost of health care. Nearly all discussions of health policy now focus on the problem of cost containment in health care and what to do about it. Almost without exception, these discussions begin with a recitation of cost escalation data,[12] including such items as per capita expenditure levels and, most important, the percentage of the gross national product devoted to health care services.[13] A natural outgrowth of this focus has been widespread discussions of how such services might better be allocated or rationed -- by both the government and private decision makers -- in order to combat the problem of cost escalation.[14] The major focus of this section is the effect of legal constraints on the process of rationing and/or allocating medical care, and the substantive criteria by which government and private decision makers undertake such allocation, with particular emphasis on heart transplantation.

B. ALLOCATION AND RATIONING OF HEALTH CARE RESOURCES

Of all of the crises in resources that the United States is expected to face in the future, the problem of resource distribution in health care is likely to be the most acute.[15] Individuals will be identified as in need of, and then denied benefits that the health care system is capable of providing. Instead of an unidentified group of anonymous individuals being denied access to a needed resource, identifiable individuals will be declared ineligible for a treatment or a service that they are known to require.[16] Health care technology now permits lives to be saved than less than a decade ago would surely have been lost. Moreover, technology has made it exceedingly difficult to specify at precisely what point life itself ceases. This situation has prompted Crane to conclude that both health care and law are moving toward a "social interpretation" of life.[17]

It should come as no surprise that the resources available to meet the demand for health care are limited[18] and that some form of allocation is necessary. Weinstein and Stason, for example, have pointed out that such decisions are already being made -- physicians allocate their time, hospitals ration beds, fiscal intermediaries devise reimbursement policies -- all of which suggest that priorities are being set.[19] This is not to suggest that such problems have historical roots in times past. Even a few decades ago, prior to the proliferation of medical technology and the pervasiveness of health insurance, constraints on health care resources were largely unheard of. In the past, the distribution of health care resources was

accomplished by implicitly limiting their availability or when available, restricting people's access to them.[20] Thus, the concepts of availability and accessibility are critical to the problem of health care resource distribution.[21]

Rationing is the term often used to describe the process of differentially distributing resources. However, it has become a value-laden term -- one that implies that people are likely to be treated unequally.[22] Allocation is another term often used to describe the unequal distribution of resources. While Webster's New World Dictionary defines rationing as "a fixed portion; share; allowance," allocation is defined as to "set apart for a specific purpose, to distribute according to a plan."

As suggested by the definitions or rationing and allocation, there is merit in distinguishing between the allocation and rationing of health care resources. Others have used the terms "macroallocation" and "microallocation" to make a similar distinction.[23] Regardless of the terms used, however, it should be recognized that allocation and rationing differ both with regard to timeframe and level. First, allocation decisions are likely to precede rationing decisions. Second, allocation is a concept that does not apply easily at the level of the individual patient, but rather is more appropriately applied at the aggregate or health care program level.

Once it is apparent that all who are in need cannot be treated, the question then becomes one of determining which potential recipients will derive the greatest benefit from a program or treatment. Again, this is precisely what occurred during the early

years of kidney dialysis, when patients were selected by physicians or committees. At that time, it was decided that although all kidney disease patients ultimately had a terminal condition, some had better prospects for treatment than others.[24] The preferred candidates were selected on the basis of a variety of criteria, such as age, medical suitability, mental acuity, family involvement, criminal record, economic status (income and net worth), employment record, availability of transportation, willingness to cooperate with the treatment regimen, likelihood of vocational rehabilitation, psychiatric status, marital status, educational background, occupation, and future potential.[25] These criteria served as the basis upon which scarce resources were rationed. Similar criteria are currently used to select potential heart transplant recipients and thus serve as a similar rationing mechanism.[26] Although the decision to extend Medicare benefits to kidney patients resolved the rationing problem for the federal government, Evans noted that the government ". . . appears to have been more concerned with ridding itself of the moral dilemma of indirectly deciding who could live and who would die in a country of almost unlimited resources," rather than simply trying to deal with the more general problem of costly medical care.[27]

Now that the government is at least willing to entertain the possibility of differentially allocating resources to health care, it inevitably will also have to entertain the need to ration health care resources between competing needs at the program level. Should resources be further constrained, it may become necessary to ration the available resources to individuals, perhaps based on a set of uniform guidelines.

The foregoing discussion raises two important questions that have yet to be addressed. First, on what basis will resource allocation decisions be made, and second, how are criteria for rationing likely to be developed? The first issue is a political question, beyond the scope of this report. The second issue raises the question of the legal constraints on rationing criteria, the focus of the material below.

C. PUBLIC AND PRIVATE DECISION MAKING

The distinctions between governmental and private decision making on the one hand and allocation and rationing on the other hand on are important factors in considering constitutional constraints on such decisions. For example, the government can allocate public funds to medical care,[28] and it can constrict the use of private funds for the purchase of medical services, equipment, and other medical supplies.[29] The government can also circumscribe the autonomy of health care practitioners in their professional activities.[30] Moreover, these decisions can be made both at the programmatic (allocation) and individual (rationing) levels. For example, allocation could involve a legislative or administrative decision about whether heart transplantation should be covered under the Medicare program,[31] or a governmental choice to sponsor further research on cancer but not on heart transplantation. An example of a rationing decision would be the establishment of patient selection criteria and the determination of whether a person otherwise eligible for governmental benefits (such as heart transplantation) under a

particular program, qualifies for treatment under a given set of circumstances. Understanding these distinctions is particularly important in the analysis of procedural due process constraints on such decisions.

When the government allocates public funds, disappointed claimants may allege that the government action is impermissibly discriminatory and denies them equal protection of the laws.[32] Alternatively, claimants may argue that the government is breaching some affirmative duty toward them in such a way as to deny them life, liberty, or property under the due process provisions of the 5th or 14th amendment. Finally, when the government, through a rationing decision, restricts the ability of an individual to spend money on the medical services of his or her choice, the likely claim would again be that the government is overreaching in an area protected as life, liberty, or property without due process of law. The material below discusses each of these issues in more detail.

D. EQUAL PROTECTION

The equal protection clause mandates that the government treat similarly situated people in a like manner. When, in allocating scarce medical resources, the government classifies a certain group of individuals as eligible for a given benefit, thereby implicitly (and often explicitly) excluding others, members of the disadvantaged or excluded group can require the state to articulate "legitimately defensible differences"[33] to justify the disadvantageous distinction. The essential equal protection inquiry is the determination of the content of the state's burden of justification.

1. RATIONAL RELATIONSHIP

Equal protection doctrine imposes a heavy burden on states only when a classification impinges on a fundamental interest or applies a basis of classification that is constitutionally disfavored. In traditional equal protection analysis, the courts have afforded a presumption of validity to government classifications. The state must have a legitimate purpose, and the means used to achieve that purpose must be rationally related to it. However, the range of legitimate state interests is broad, and the courts generally will not examine the weight of those interests. The burden rests on the plaintiff to show that a classification is "wholly irrelevant to the achievement of the state's objective."[34] The legislative rational does not even have to be supported by empirical evidence -- the state need only make a reasonable, logical case for its classification, even if its legislative judgment turns out to have no basis in fact.[35] Consequently, unless a plaintiff can find a reason for the application of a stricter standard of review, the Supreme Court will almost always deny an equal protection challenge to a legislative classification.[36]

In the area of economics and social welfare, the Supreme Court has been unwilling to become involved in the "intractable economic, social, and even philosophical problems presented by public welfare assistance programs."[37] and the Court has refused to "second guess state officials charged with the difficult responsibility of allocating limited public welfare funds among the myriad of potential recipients."[38] The Court has declined to label as fundamental such matters as education,[39] welfare,[40] and housing.[41] And in the

abortion funding cases, the Supreme Court declined to hold medical care to be a fundamental interest.[42] The Court, therefore, has subjected these social welfare programs only to minimal scrutiny.

2. STRICT SCRUTINY

The disfavored classification theory holds more promise as a limitation on overtly aggregious systems of classification.[43] Classifications deemed suspect, such as race,[44] must be justified as necessary to promote a compelling state interest.[45] Under this test, the Supreme Court examines the strength of the governmental interest involved, not merely its legitimacy. In addition, the Court carefully scrutinizes the means adopted by the state to achieve its goal and examines the availability of alternatives that would avoid the use of suspect classifications. Finally, the Court does not apply a presumption of validity to such classifications, so the state faces a more difficult burden of justification. Where a racially-based classification has been implemented, at least to the disadvantage of a minority,[46] the state has a virtually impossible obstacle to overcome. Consequently, a racially based classification, even for social welfare allocations, would almost certainly be held invalid.

3. SUBSTANTIAL RELATIONSHIP

Although the Supreme Court continues to maintain that it applies a two-tiered level of scrutiny, rational basis and compelling interest, in at least one case the Court has also adopted what appears to be an intermediate standard of review in the case of disfavored classifications that the court is unwilling to label as suspect.[47] The clearest example of this intermediate level of scrutiny comes in

the area of gender-based classifications. Although the court has backed away from this position,[48] at one time, four of the court's nine justices were willing to declare gender a suspect category.[49] Nevertheless, the Court's scrutiny in gender cases is clearly stricter than the traditional rational basis review. The decision in Craig v. Boren[50] established the controlling standard of review in gender related cases: "to withstand constitutional challenge, classifications by gender must serve important governmental objectives and must be substantially related to the achievement of those objectives."[51] This test suggests that the Supreme Court will examine the strength of the state's interest, requiring it to be more than merely legitimate but less than compelling. The scrutiny of the states' approach under this standard affords less discretion for a state than the rational relationship test, but more flexibility than the compelling interest test.

4. DISCRIMINATORY INTENT AND DISCRIMINATORY IMPACT

Equal protection analysis does not end with the recognition that the courts have given greater constitutional scrutiny to suspect and disfavored classifications. Because overt racial classifications are now rare, and overt gender-based classifications are becoming less frequent, equal protection analysis often requires a detailed inquiry in order to determine whether a classification is based on suspect or disfavored criteria. The Supreme Court has delineated the general rule that the proof of both racial and gender classifications must include evidence of discriminatory intent. In Washington v. Davis,[52] the Court established the rule that proof of discriminatory intent is

necessary to demonstrate a race-based classification. Discriminatory purpose, not disparate impact, is the core of the constitutional violation. In Personnel Administrator v. Feeney,[53] the Court applied the same standard of proof to a gender-based discrimination. There, the Court held that a law must be designed to prefer one sex over the other in order to qualify as a gender-based classification. Plaintiffs must show that "the decision makers selected or reaffirmed a particular course of action at least in part because of, not merely in spite of, adverse affects upon an identifiable group."[54]

E. PROCEDURAL DUE PROCESS: THE STATE ACTION REQUIREMENT

The due process provisions of the 5th and 14th Amendments have both procedural and substantive requirements. In either case, however, a threshold issue in analyzing whether a due process violation has occurred is the existence of state action.

1. STATE ACTION

In order for the provisions of the 5th and 14th Amendments to be applicable at all, the decisions at issue must be either made directly by governmental bodies, or by private authorities whose actions can be fairly attributable to the government.[55] For example, purely private patient selection decisions made by physicians in the ordinary course of their practices are not likely to be attributable to the state. However, the government is involved in the health care delivery system in a variety of ways, and under such circumstances that the constraints of the constitution do apply. For example, the government directly finances health care through the Medicare and

Medicaid programs, which involve both the establishment and the application of eligibility criteria for recipients. In some cases, governmental entities, such as state and local hospitals, are involved in the direct provision of care to specific beneficiary groups.

When the government directly allocates public funds for the provision of health care services, the state action requirement is easily met. Similarly, state action is present when the government establishes criteria for program eligibility, or makes determinations concerning individual qualifications in specific cases.[56]

For years the Supreme Court has sought an appropriate way to distinguish between government and private responsibility for decision making. Much of the state action doctrine developed by the Supreme Court arose from the civil rights litigation of the past three decades. Before the enactment of the major civil rights legislation of the 1960's, blacks could not sustain claims of discrimination unless they could somehow demonstrate government responsibility for the allegedly discriminatory acts. Federal constitutional guarantees were not applicable in the absence of state action, and no specific civil rights legislation existed to eliminate private forms of discrimination in areas such as public accommodations, employment, and housing. In order to remedy these ills, the Supreme Court developed and endorsed an expansive definition of state action.[57]

More recently, however, the decisions of the Court indicate that it has backed away from this far reaching approach to state action. These recent decisions indicate that the Court has become increasingly willing to define behavior as private activity, not

subject to constitutional limitations.[58] This trend suggests that the government may now be able to implement successfully a strategy of keeping distance between itself and the ultimate allocation and rationing decisions in the provision of health care services.

Traditional state action analysis had two dimensions. On the one hand, the nature and extent of government participation in, and support of a private party's conduct was used to justify a finding of state action.[59] The other strand of the doctrine held that private action that performed a governmental or public function could be justifiably attributable to the state.[60] In the last ten years, the Supreme Court has narrowed the participation theory,[61] and virtually eliminated the public function theory.[62]

2. DEPRIVATION OF CONSTITUTIONALLY PROTECTED INTERESTS

Once a court finds that conduct is attributable to the government on the basis of state action, it triggers the safeguards of the 5th and 14th amendment that apply only to life, liberty or property interests within the meaning of these amendments. At the threshold, "to determine whether due process applies in the first place, we must not look to the weight but to the nature of the interest at stake."[63] Interests protected by due process are those to which a individual has a legitimate claim of legal entitlement, not a mere unilateral expectation.[64]

In Board of Regents v. Roth,[65] and in subsequent decisions, the Supreme Court has made it clear that protected property interests are established by reference to statutes, regulations, administrative practices, contractual arrangements, and other forms of mutual and

consensual understanding, not by reference to the constitution itself. In each case, an individual must have a legally cognizable and enforceable interest. The protection of procedural due process is designed to safeguard individuals against arbitrary governmental action that "seeks to remove or significantly alter that protective status."[66]

In Roth, an untenured college professor claimed that he was entitled to notice and a hearing to dispute nonrenewal of his teaching contract. The Supreme Court held that the state had discretion to decide whether to retain Roth, without providing a hearing or other aspects of due process, because he had no legally enforceable claim to reemployment after the expiration of his contract. He was, of course, free to apply for renewal, just as any applicant who is eligible for a job may apply for it. However, the fact that he met the minimum qualifications for the position was not sufficient to give rise to a protective entitlement to the job. Possession of those minimum qualifications created more of a unilateral hope or expectation to which due process guarantees are simply not applicable.

3. PRESENT ENJOYMENT OF BENEFITS

The cases also suggest that the due process clause protects only the "present enjoyment" of an entitlement. Thus, in Roth the Supreme Court observed that "the 14th Amendment's procedural protection of property is a safeguard of the security of the interest that a person has already acquired in specific benefits."[67] Similarly, in Paul v. Davis,[68] which rejected a claim to deprivation of a persons "liberty" interest in his reputation, the Supreme Court noted that

state law did not grant "any legal guarantee of present enjoyment of reputation"[69] that was impaired by the action of public officials. Finally, in Greenholtz v. Inmates of the Nebraska Penal and Correctional Complex,[70] the Court observed that "there is a crucial distinction between being deprived of a liberty one has, as in parole, and being denied a conditional liberty that one desires."[71] Chief Justice Burger agreed that "there is a human difference in loosing what one has and not getting what one wants."[72]

In summary, the due process cases suggest that both the legislative and executive branches of the government will be able to make broad rationing and allocation decisions free from procedural due process scrutiny. In terms of specific patient selection criteria for heart transplantation, the application of due process principles may depend significantly on the specific provisions of the legislation and administrative regulations governing a particular program. If the government establishes transplantation as a Medicare entitlement, where a beneficiary is entitled to a transplantation upon meeting certain specified patient selection criteria, due process safeguards will continue to apply under the dictates of Goldberg v. Kelly. Any similar medical benefits program for heart transplantation that conferred benefits as a matter of right upon a beneficiary who satisfied certain objectively determinable criteria would also create a protective entitlement under due process. The "present enjoyment" limitation, however, could be construed to distinguish between an applicant for such a program, and an actual beneficiary facing a benefits cutoff. Thus, Medicare beneficiaries could exert a claim for

transplantation not exercisable by a similarly situated individual not covered by Medicare.

F. DUE PROCESS PROCEDURES

If the threshold requirements of the 5th and 14th amendments, i.e., state action and deprivation of a protected interest are met, then procedural due process guarantees will apply. Determining what process is due, however, depends on an ad hoc balancing process. The Supreme Court has often noted that due process protection is only intended to assure basic fairness in the adjudication process, and is not a "technical conception with a fixed content unrelated, to time, place and circumstances."[73] The requirements of due process have extended from the elaborate trial-like procedures mandated in Goldberg for welfare terminations, to an informal give and take in school disciplinary proceedings.[74] And in some situations, the Supreme Court has found no need for any hearing whatsoever when after-the-fact remedies satisfy the requirements of due process.[75]

The Supreme Court established the general balancing approach in this area in Matthews v. Eldridge,[76] which involved the termination of disability benefits under the social security program. There the Court stated that the:

> identification of the specific dictates of due process generally requires consideration of three distinct factors: #First, the private interest that will be affected by the official action; second, the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and finally, the government's interest, including the function involved and the fiscal and administrative

> burden that the additional or substitute procedural requirements entail.[77]

In essence, the balancing formulation in Matthews means that each situation will require independent ad hoc analysis.

1. FORMAL STANDARDS AND ADMINISTRATIVE DISCRETION

One procedural requirement often sought in due process cases is the adoption of formal standards, such as a set of strict patient selection criteria, to constrain the discretion of the decision making body. Those seeking the adoption and publication of such standards generally believe that rule making serves to increase governmental accountability and restrain arbitrariness. A countervailing concern, however, is the problem of legislative or administrative foresight and lack of flexibility. The flexibility, possibly increased precision, and opportunity for the exercise of compassion in individualized decision making counterbalances the benefits of the objectivity and limits on arbitrariness inherent in informal standards.

The imposition of a requirement to articulate and publish patient selection criteria for heart transplantation creates problems for governmental decisions to ration or allocate health care services. Although some courts in the 1960's held that public agencies had an obligation to adopt selection criteria for public housing,[78] and standards for the allocation of liquor licenses,[79] it is unclear whether these cases would survive the entitlements approach that have controlled due process analysis since the 1972 decision in Roth.[80]

Blumstein notes that the analyses presents a "chicken and egg" problem.[81] If no entitlement exists, then no due process

applies. Yet it is difficult to see how an entitlement can exist unless objective selection criteria are already in existence. An individual's general eligibility for a benefit is insufficient to warrant designation of that benefit as an entitlement. Consequently, due process should not require the articulation of specific selection criteria because, in the absence of such criteria, no entitlement exist for due process purposes.

The government could, as a matter of policy, choose to establish and publish allocation criteria for heart transplantation. One likely outcome of such an action would be the creation of an entitlement to a heart transplant that would grant specified individuals the rudimentary due process rights of notice and a hearing upon denial of their access to this procedure. While the desirability of reducing arbitrariness is undeniable, the articulation of clearly formulated patient selection criteria poses substantial problems.

Pragmatically, formulating such criteria is difficult because of the variety of problems and nuances that inevitably arise in the heart transplant context. More importantly, there is the spectre of the government openly renouncing the widely held belief in the sanctity of human life, and publicly acknowledging that society is unwilling to expend the funds necessary to preserve human life and health. In short, as the kidney dialysis experience demonstrated,[82] the formulation of explicit selection criteria can have a devastating effect on deeply held symbolic values, especially since such decisions can often have an immediate impact on clearly identifiable individuals.

In these situations involving tragic choices, the use of what Calabresi and Bobbitt call "a-responsible agencies" may serve a useful function.[83] Ad hoc, standardless decisions like those of juries or hospital committees, for example, have an idiosyncratic character that disguises the weight being assigned different variables and blurs the hierarchy of values chosen. The informal nature of these decisions and the lack of specifically articulated criteria mitigate the "devastating impact of complex and hard choices" that are implicitly being made.[84]

G. SUBSTANTIVE DUE PROCESS

The due process clause also operates as a substantive limitation on the extent to which the government can exercise its power. Although at one time substantive due process notions were widely invoked to limit the exercise of governmental authority, the doctrine has gradually evolved to the point that the courts will no longer rigorously scrutinize governmental action under substantive due process. In general, courts will sustain legislation that serves a legitimate public interest if the means chosen to carry out the legislative purposes are rational. This statement of the "rational basis" standard of review does not fully convey the extent of the Supreme Courts' deference to governmental action. In essence, substantive due process review is a mechanical process that almost always results in the validation of the challenged governmental action.[85]

There are two exceptions to the extraordinary deference that is accorded governmental action. First, where the Supreme Court deems individual liberties to be fundamental, it requires the government to show that its legislation is necessary to achieve a compelling state interest.[86] Thus, it is well settled that "if a law impinges upon a fundamental right explicitly or implicitly secured by the constitution it is presumptively unconstitutional."[87] Second, the government is not accorded such deference in the rare cases in which the Supreme Court has recognized an affirmative obligation on the part of the government to provide access to specific services. Some commentators have argued that the government has an obligation to provide access to medical services,[88] but the Supreme Court has explicitly refused to recognize the constitutional foundation for such a right outside of the prison context.[89]

The abortion funding cases, Roe v. Wade, Maher v. Roe and Harris v. McRae,[90] are the most instructive and explicit in regard to this principle. The lesson to be learned from Maher and McRae is that the government has broad powers in the distribution of its health care resources. The two decisions draw an important and fundamental distinction between an individual's right to be free from governmental interference, which may well receive strict constitutional protection, and a claimed constitutional right to have government funds allocated to pay for these private choices. Both Maher and McRae rejected the latter claim.

In addition to raising the alleged infringement of a privacy interest recognized in Roe v. Wade, individuals who are denied access

to a heart transplant may argue that the government has an affirmative duty to provide access to health care services for those who are unable to afford to pay for their own care. The Supreme Court has held that in some cases indigent individuals indeed may have a claim to government supported access to certain services. This doctrine originally arose in the criminal justice context, but the Court has extended it to include a limited number of other governmental duties.[91] The Supreme Court, however, has recognized only a narrow range of cases in which it will impose such an affirmative funding obligation. These cases are characterized by the importance of the services involved and their "constitutional connection,"[92] the degree of state monopolization of access to them, and the element of total deprivation based on lack of funds.[93]

In Maher, the Supreme Court made it clear that the right of access cases would not be applied in the context of health care services. The Court noted that the state had made no effort to monopolize the means for terminating pregnancies through abortions -- it had merely refused to finance them. Unless the government's control over the health care system becomes absolute, analagous to its regulation of the court system or the criminal justice process, the Supreme Court seems unlikely to conclude that individuals have an entitlement to governmentally provided health care services.

The only area in which the Supreme Court has imposed an affirmative duty on government to provide health care services is for incarcerated prisoners. In Estelle v. Gamble,[94] a prisoner alleged that inadequate treatment of a back injury constituted cruel and

unusual punishment in violation of the 8th Amendment. Although the Supreme Court ruled against the prisoner, Justice Marshall distinguished the prisoner's claim, which was based on poor quality treatment and bad medical judgment, from an allegation of "deliberate indifference to a prisoners serious illness" and his "serious medical needs," which would constitute cruel and unusual punishment under the 8th Amendment. The Court thus found that the government had an "obligation to provide medical care for those whom it is punishing by incarceration,"[95] since "an inmate must rely on prison authorities to treat his medical needs."[96]

Gamble illustrates how difficult it is for the government to deny medical treatment after the establishment of a governmental responsibility and an accompanying relationship of dependence. However, as a practical matter, the right to treatment recognized in Gamble will likely have little impact outside of the criminal justice system. In Ingraham v. Wright,[97] which involved the disciplinary paddling of a public school child, the Supreme Court held that the cruel and unusual punishment doctrine did not apply outside the criminal law area. Justice Powell expressly distinquished the two situations on the ground that "the prisoner and the school child stand in wholly different circumstances, separated by the harsh facts of criminal conviction and incarceration."[98]

Section 2 - GOVERNMENT REGULATION OF HEART TRANSPLANTATION

A. INTRODUCTION

If the right to choose to undergo a particular form of medical treatment is recognized as a protected aspect of the right of privacy, the courts then will have to examine the permissible limits of governmental regulation of medical procedures such as heart transplantation. Under constitutional privacy standards, the validity of state involvement may depend on the form of governmental action--whether it involves direct regulation or reimbursement limitations--and the goals that the state seeks to advance through such regulation. As already noted for example, the government may institute a policy of refusing to reimburse or limiting reimbursement for particular medical services and procedures that it finds to be insufficiently cost-effective. It could also choose to limit reimbursement by allowing payment only for procedures performed at particular facilities (or by particular surgeons).[1] This type of limited reimbursement plan might be viewed as a means to facilitate efficient use of expensive and scarce equipment and personnel, reduce oversight and regulatory burdens, and perhaps even as a means of capping costs because it would limit the number of reimbursed procedures to the number that the chosen facilities or surgeons could accommodate. Policymakers may also favor such a system because they feel success ratios may be enhanced by limiting reimbursement to physicians or centers with proven records of success.

With these distinctions in mind, we can begin to grasp the issues involved in the debate over regulation of medical procedures in general, and heart transplantation in particular. The remainder of this section explores possible limitations on the ability of the government to regulate heart transplantation, first focusing on constitutional limitations on direct regulation, and then shifting to permissible uses of the spending power.

B. DIRECT REGULATION UNDER THE COMMERCE OR POLICE POWER

In a recent article,[2] Blumstein suggested that the government has relatively broad latitude in regulating medical practice and procedures.[3] He stated that the government can both limit the accessibility of the marketplace to persons who do not meet basic licensure standards, and can circumscribe the ability of practitioners to follow their own medical judgment in certain situations.[4] Thus, he argued, the state and federal governments can outlaw the administration of certain treatments (such as laetrile) unless the restrictions have an unconstitutional impact upon the patient's fundamental interests, as in contraception and abortion.[5] This analysis accurately states the current status of the law. If, then, the right to choose to undergo particular forms of medical treatment is accorded similar status as the abortion and contraception rights, regulations that appreciably reduce the ability of the individual to privately purchase a particular medical procedure would presumably be subject to the same constitutional norms. Thus, such regulations

would have to be justified by a compelling state interest, and be tailored to infringe as little as possible on the decisional right.

The right of privacy cases involving abortion and contraception indicate the analysis that the Supreme Court likely would take in a case involving a fundamental right to undergo treatment. In those contexts, the Court previously has held that the strict scrutiny test applies both to regulations that substantially limit access to the means of effectuating a protected choice, and to regulations that outlaw a protected choice entirely.[6] But it must be governmental action that limits the choice, not a preceding condition of the person. For example, in Maher v. Roe and Harris v. McCrae,[7] the abortion funding cases, the Court made it clear that the access restriction must be one that does not result from a reduction or elimination of state subsidization of one of the choice alternatives. Yet, the Court emphasized that in these cases it was not an access restriction that made it difficult or impossible for some women to effectuate their choice right to obtain an abortion. Rather it was indigency--a non-state created limitation, and that this limitation existed prior to any state action in the field. Since the fundamental choice right was not infringed, limitations on Medicaid funding for abortions were examined under the rational basis test and adjudged permissible.[8] As is explained more fully below, a decision not to fund, or to limit Medicare reimbursement for, heart transplantation would be examined under a similar analysis and therefore would, in all likelihood, be adjudged permissible.

Direct statutory or administrative regulation of medical procedures that result in reduced accessibility to everyone, however, could be subject to a much higher level of constitutional scrutiny, because in the funding cases,[9] the Court repeatedly distinguished refusals to reimburse from direct regulations limiting the performance of abortions or availability of contraceptives. Regulations that impose a "penalty," "direct burden,"[10] "absolute obstacle,"[11] or "unduly burdensome interference with the freedom to decide whether to terminate a pregnancy"[12] must meet a standard more exacting than the rational relationship test.[13] It is difficult to speculate about the exact form regulatory procedures for heart transplantation would take. However, it is clear that if the right to make important decisions affecting medical treatment is accorded constitutional status, and the analysis set out in the abortion and contraception cases is followed, the state may have to come forward with compelling justifications for any regulations that reduce the individual's ability to effectuate a decision to undergo a medical procedure such as heart transplantation.

The government's latitude to regulate in the area, however, may not be significantly affected for two reasons. First, the Supreme Court has recently emphasized the notion that regulations must <u>unduly</u> burden an individual's decisional right before they will be closely scrutinized at all.[14] Second, courts have always recognized that the state has a strong interest in promoting the safety and efficacy of medical procedures and drugs,[15] and have traditionally accorded wide latitude to the state and federal governments to regulate in that

area. Thus, a heart transplantation regulation might not be subjected to strict scrutiny unless it reduced the availability of the procedure (possibly to some threshold level). Moreover, even if such a regulation was found to impinge upon the right to make independent decisions about medical treatment, the state may have an interest sufficient to allow narrowly drawn regulation.

The case of Andrews v. Ballard, discussed earlier,[16] illustrates this doctrine. The case involved a challenge to regulations limiting the practice of acupuncture to licensed physicians. The plaintiffs argued that the regulation severely limited their ability to obtain acupuncture treatment and therefore violated their right to decide to undergo such a treatment. While the court recognized the privacy right, the state argued that the physicians-only requirement was needed because of the unproven safety and effectiveness of acupuncture.[17] The court, however, rejected the contention after reviewing evidence of the safety and effectiveness of acupuncture treatment.

The state also asserted that the physicians-only requirement protected patients from misdiagnoses; the licensed physician, the state asserted, would be more likely than a non-physician to accurately diagnose any underlying medical disorder and treat it appropriately.[18] The court noted, however, that the physicians-only requirement was not the narrowest means of effectuating the state's compelling interest in prevention of misdiagnoses. Judge McDonald suggested that an equally effective but less restrictive alternative

would be to simply condition the patient's right to undergo acupuncture upon prior consultation with a physician.

The state next argued that the requirement assured that acupuncture would be properly administered.[19] Judge McDonald determined that, although the state's interest in proper administration of acupuncture might be compelling, the physicians-only requirement was not sufficiently narrowly drawn and, in fact, was actually detrimental to the state's objectives. The court pointed out that while an overwhelming proportion of Texas physicians are totally unfamiliar with both the theory and practice of acupuncture, many acupuncturists have both training and expertise in acupuncture technique and theory, as well as basic anatomy. The court then attacked the Act for prohibiting the formally trained (acupuncturists) from practicing while allowing the admittedly unskilled (physicians) to practice without any showing of skill or knowledge in acupuncture.

Finally, the state argued that the ban on acupuncture by non-physicians was necessary to ensure that the patient's health would be adequately protected in the event that medical complications occurred during treatment. The court rejected this line of reasoning, noting that although complications during acupuncture treatment were unlikely, assuring that they would be remedied quickly was a legitimate state interest.[20] However, the Act was insufficiently tailored to the objective, because alternative, less intrusive means of meeting that objective were available. The state, the court reasoned, could require acupuncturists to pass courses in emergency medical treatment, or require that they assure that their patients

have ready access to a physician, or in some way have emergency treatment readily available. The court noted that any of these alternatives could protect the state's interest in adequate treatment of complications without unconstitutionally interfering with the patient's rights.[21]

If the courts analyze attempts to regulate heart transplantation as the Andrews court did the Texas acupuncture regulations, then regulations that reduce (perhaps to some threshold level) access to heart transplantation must be both justified by a compelling state interest and narrowly drawn. But what are the interests that the state may legitimately assert in support of regulation of transplant activities?[22]

C. STATE INTERESTS IN REGULATING HEART TRANSPLANTATION

1. SAFETY AND EFFICACY

Assuring that the public is not exposed to medical practices that are unsafe or inefficacious would undoubtedly be a major governmental objective in enacting any form of regulation of heart transplantation. Commentators have expressed concern, for example, that unrestrained governmental reimbursement for heart transplantation could lead to the proliferation of inadequately equipped transplant facilities, or the rapid influx of insufficiently trained surgeons into the field.[23] One possible means of effectuating this interest would be to enact state or federal licensure laws for transplant centers and/or surgeons that specify certain standards that must be met before heart transplantations may be undertaken. Such measures

may well be constitutionally valid under a strict scrutiny analysis, for Roe v. Wade established that the state's interest in preserving and protecting the health of the patient may be a compelling one.[24] Courts also have long recognized that legislative regulation of the medical profession is a proper function of a state's regulatory power. Dicta in the Whalen opinion, that seemingly recognized the fundamental right to make certain decisions independently, also stressed this proposition.[25] Thus, the state may properly assert a public safety interest in the regulation of heart transplantation.

To pass constitutional muster, however, such regulation must also be necessary to the protection of the patient's health;[26] if there are other reasonable ways to achieve those goals with a lesser burden on constitutionally protected activity, the state may not choose the way of greater interference.[27] The safety and effectiveness of a given medical treatment will, of course, influence what regulations are necessary to protect the patient's health. If a particular treatment is so unsafe or ineffective as to constitute a positive danger to those using it, a ban of the treatment might be considered sufficiently "narrowly drawn" to achieve protection of the patient's health. That is the precise argument raised in the laetrile cases.[28] However, concern over heart transplantation has not focused solely on the safety or efficaciousness of the procedure per se, but rather on its safety in particular settings, and its safety when performed by different individuals. Thus, the state would probably not be justified in banning the transplant procedure on safety or efficacy grounds in general, as the safety interests it

could properly assert could be met by less drastic means. Narrowly drawn regulations aimed at assuring that providers have sufficient proficiency and equipment, however, would appear to be justified under existing case law.[29]

2. EFFICIENT USE OF SCARCE RESOURCES

The limited supply of donor organs, as well as necessary equipment and personnel, imposes an absolute limitation on the number of transplants that can be performed at any given time, with shortages of this type possibly continuing indefinitely; it may therefore be crucial, in the coming years, to use these resources as judiciously as possible.

Obviously, there are many ways in which the state could regulate in an effort to achieve more efficient allocation of resources. A physician or facility licensure law could serve this objective, and the objective of assuring high quality care as well.[30] Higher mortality rates or greater incidences of complications would undoubtedly be associated with insufficiently skilled transplant teams or inadequately equipped centers, and could compel referring physicians to send their patients elsewhere, thus leading to underutilization of the transplant facility. Ultimately, the original expenditure of funds on specialized equipment and personnel (and possibly on patient reimbursement)--much of which may come from government sources--may produce a program of questionable benefit. The state may, therefore, have an efficiency based interest to assert in saving as many lives as possible through efficient allocation of these valuable resources.

3. HOSPITAL SOLVENCY

As a result of poor planning, a desire to attract "glamour" personnel, or simply out of a desire to save people's lives, many hospitals may decide to undertake transplant programs. The unlimited diffusion of transplant centers, however, could have an adverse impact on hospital solvency and health care insurance premiums. Particularly if little in the way of federal assistance for heart transplantation is available, many hospitals could follow a pattern that typically arises when they have unreimbursed costs--the patient is charged a fraction of the actual cost of the services he or she receives, and the remaining expenses of operating the program are amortized across the hospital's entire patient population. Because of the amortization process, health care costs for all could rise, and ultimately could contribute to the trend toward higher insurance premiums. Because the costs would also be amortized across the the general Medicare and Medicaid populations, indirect federal reimbursement for the procedure and its associated costs could occur even if the government limited Medicare reimbursement for heart transplantation.

The goal of controlling health care costs could also lead the government to restrict all heart transplantation activity to particular, perhaps publicly funded, centers. As with regulation to promote efficient allocation of resources, the individual patient's ability to effectuate his or her decisional choice may be appreciably narrowed; such regulation may curtail transplant activity and thus artificially limit the number of patients who can undergo the procedure. In addition, persons who are not located near one of the

chosen centers may have no means to pay for the increased travel and living expenses associated with seeking treatment at a distant transplant center..

Despite the assertions in this and the prior subsection, we know of no cases that hold that the government has a compelling interest in promoting hospital solvency or efficient allocation of scarce resources. These arguments may well be raised, however, if the right to undergo treatment is accorded broader recognition, and if the current trend toward regulation of expensive forms of medical treatment continue. And to the extent that they may be subsumed under a general notion of assuring adequate levels of health care, such interests may well be accorded "compelling" status. The government may thus be able to justify regulation of heart transplantation on these bases as well.[31]

4. EQUITY OF ACCESS

One of the main foci of health policy debate in recent years has been equity of access to health care. One way to seek to provide more equal access would be to assure that all individuals have the financial resources needed to seek out and obtain needed health care. Alternative policies might be to limit the total number of heart transplants and to reimburse fully all patients selected, or to ban the procedure altogether. While these possibilities appear to verge on science fiction, they have been advanced (although somewhat facetiously), in the literature,[32] although there has been no legal consideration of this objective as a justification for limiting access to a medical procedure. It is difficult to speculate on how the

courts would react to the assertion of an interest in equal access as a basis for regulating a constitutionally protected activity. Unless such an objective is judicially recognized as compelling, however, it may not be used to limit the ability of individuals privately to purchase medical care.

These are by no means the only interests that the state could assert to support various types of regulation of heart transplantation. The interests discussed, however, do indicate that the government has at least one--and perhaps several--interests that could be characterized as compelling and would therefore justify some type of regulation of heart transplantation. It must be borne in mind, however, that legislation that substantially affects access to a medical procedure would, under a strict scrutiny analysis, have to be narrowly tailored. Thus, even where the government is justified in regulating, it does not have as broad a latitude as it would have if the right to undergo treatment is not accorded a fundamental status.

D. REGULATION THROUGH THE FUNDING POWER

While the government may choose to regulate directly the availability or performance of certain surgical procedures, it also could affect treatment availability through the use of the spending power--through funding allocation, and through placing conditions on receipt of federal funds that effectively regulate how, when and if certain medical procedures will be performed. This section discusses two constitutional issues that could arise should the government undertake actions that affect heart transplantation via the spending

power. First, does the right to decide to undergo a method of treatment limit the government's ability to exclude such treatment from coverage under Medicare or Medicaid? Second, what is the extent of the government's ability to regulate the performance of heart transplantation under the spending power? May it attach conditions that apply outside of the Medicare program to all transplantation activity? If it does so, would such a practice be subject to constitutional limitations via the potential transplant recipient's privacy right? These topics are discussed in turn below.

1. DOES THE RIGHT TO DECIDE ENTAIL A RIGHT TO EFFECTUATE?

The right to decide to undergo a method of treatment is inescapably linked to the question of payment for that treatment. To the individual in need of a heart transplant, a "right" to choose such treatment may seem rather empty if he or she cannot obtain the financial resources to effectuate that choice. While the high costs associated with research and development during the initial years of heart transplantation are ending, the procedure is nonetheless costly.[33] As heart transplantation moves in the future from a quasi-experimental procedure to a generally accepted form of therapy, many persons who would otherwise be considered good candidates for transplantation will be excluded from transplant programs solely because they do not have the requisite financial means to avail themselves of treatment.

The underlying social question is whether the ability to pay for the procedure is a fair requirement for entry into a transplant program, which raises two further questions. First, could the

legislature specifically exclude heart transplantation from Medicare reimbursement, even though it might otherwise be covered under existing private insurance policies for eligible recipients? Second, should or must the government guarantee payment for virtually all heart transplants through special Medicare coverage similar to that now provided for renal transplant and dialysis patients? These questions obviously present pressing concerns of public policy. Yet challenges to government refusals to reimburse for particular medical procedures will face few, if any, legal challenges premised on right of access or privacy infringement arguments. Even if the privacy right is found to protect treatment choice, this right does not obligate the government to pay for any particular treatment. As already noted, like the right to decide whether to bear a child, any constitutional right to choose a method of medical treatment would be a right to be free of governmental interference or restriction, and not an entitlement to public resources. Such entitlements can only be created by the legislature.

The applicable constitutional framework for this conclusion is set out in the Supreme Court's disposition of the abortion funding cases, Maher v. Roe,[34] and Harris v. McCrae.[35] Maher involved a decision by the Connecticut Welfare Department to withdraw funding for non-therapeutic abortions in its Medicaid program. The Court stated that "the constitution imposes no obligation on the part of states . . . to pay any of the medical expenses of indigents."[36] Since no right to medical services for indigents exists, the case turned only on whether some putative right to decide whether to beget children

changed that general principle. The Maher Court found that it did not. It noted that the state's refusal to pay for non-therapeutic abortions "placed no obstacles . . . in the pregnant woman's path to an abortion."[37] The Court reasoned that the woman's indigency, not the state, created her dilemma. The government's decision to refuse reimbursement for non-therapeutic abortions, therefore, did not take anything away from the indigent woman; absent a legislatively prescribed duty to provide medical services, the state's refusal to pay for an abortion created no new government restriction on the indigent's access to abortion. The Court noted generally that refusal to fund such a procedure could not be equated with denying a person the constitutional right to seek it.

In Harris v. McCrae, the challenge was to the constitutionality of several versions of the Hyde Amendment, which prohibited government payment for most medically necessary abortions. In Harris, the Court roundly dispelled any notion that the Maher holding was limited to non-therapeutic procedures. The Court acknowledged that a woman's interest in protecting her own health was an aspect of her freedom to choose to terminate a pregnancy, as that right was articulated in Roe v. Wade.[38] However, the Court noted that:[39]

> . . . it simply does not follow that a woman's freedom of choice carries with it a constitutional entitlement to the financial resources to avail herself of the full range of protected choices . . . . Although the government may not place obstacles in the path of a woman's exercise of her freedom of choice, it need not remove those not of its own creation. Indigency falls in the latter category.

As Blumstein noted,[40] these cases draw an important distinction between an individual's right to be free from governmental interference in a personal decision (that may well receive strict judicial scrutiny), and a claimed right to have government funds allocated to pay for a private choice. The Supreme Court firmly rejected this latter claim in both Maher and Harris.[41] Although these decisions involve the right to choose abortion, and not a right to choose to undergo a particular form of medical treatment, the same analysis would apply if that right were being analyzed. Thus, even if a fundamental right to choose to undergo a procedure such as heart transplantation is recognized, it does not follow, in the Supreme Court's language, that the freedom of choice carries with it a constitutional entitlement to the financial resources to avail oneself of the full range of protected choices. Absent a statutory entitlement, therefore, no individual has a constitutionally based claim of right to government reimbursement for heart transplantation. If a challenge is argued on the basis of a right to reimbursement, any decision to exclude or limit reimbursement will be analyzed under the rational basis test.

While they raise vital questions of public policy, decisions to limit reimbursement for heart transplantation to the current population of Medicare beneficiaries, to extend reimbursement outside of the currently recognized patient population, or to refuse reimbursement altogether, should be free from strict scrutiny by the courts.

2. CONDITIONS ON THE RECEIPT OF FEDERAL FUNDING

If new programs are developed that offer reimbursement for, or regulate the performance of, heart transplantation, constitutional questions surrounding permissible uses of the conditional spending power will also have to be examined. Since such regulations have not yet been enacted and we thus do not know what form they will ultimately take, our analysis will of necessity have to be tentative.

The basic constitutional principle that circumscribes the federal spending authority appears in Article I, Section 8, of the U.S. Constitution. It grants Congress the power to "lay and collect Taxes. . ., to pay the debts. . .and provide. . .for the general Welfare."[42] The concept of "general welfare" has been broadly interpreted by modern courts. At an earlier time, health care spending as an extension of the power to spend for the general welfare may have failed to survive constitutional attack,[43] but the modern view of the scope of the spending authority leaves no doubt that Congress can spend federal revenues for a broad range of health care-related items and programs.

Judicial interpretation of both the conditions that can be imposed on recipients of federal funds and the discretion that Congress has in doing so have been very liberal. The reluctance of the courts to invalidate governmentally imposed spending conditions has been based on the twin rationales that: (1) recipients remain free to forego federal funds and avoid complying with unpalatable conditions, and (2) Congress must have broad authority to control the way in which federally funded programs are administered.

While it is true that these rationales will not support unlimited extension of federal controls via spending restrictions, the scope of Congress's ability to condition acceptance of federal funds may extend further than these rationales suggest. At a time when dependence on federal monies is essential to both private and public health care institutions, the right to avoid compliance with governmental demands by opting out of federal funding is not a practical one. Imposing conditions on the recipient of federal financial assistance has become more than merely a means for controlling expenditures under one narrow program; conditions are being placed on the receipt of funds under one program to achieve policy goals that may be unrelated to that particular program. An example of such a condition is a requirement that hospitals pay for some indigent patients' medical care as a condition of receiving Hill-Burton funds for hospital construction.

While the courts since the early 20th century, have steadfastly maintained that Congress has very broad discretion in conditioning receipt of federal financial assistance, the scope of that authority may be challenged when the condition imposed "strains the logic of the traditional constitutional justifications for the conditional spending authority."[44] In examining the constitutionality of conditional spending by the federal government, the courts have frequently distinguished between spending conditions that encourage or induce compliance from those that coerce compliance.[45] Yet courts rarely invalidate an exercise of conditional spending because of coercion, and give very little content to this

limitation.[46] "Coercion" arguments have been most persuasively raised in cases involving conditions imposed on state and local governments, an argument raising the related but distinct issues of federalism and state sovereignty.[47]

If, however, the coercive effect of conditional federal spending is treated seriously as a consideration in constitutional analysis, then questions could be raised about the constitutionality of restrictions that may be imposed on institutions performing heart transplantation. For instance, almost every hospital currently depends so heavily on federal financial support, principally through Medicare and Medicaid reimbursement, that they may have little choice but to comply with conditions imposed by the federal government.[48] It would be undeniably coercive--as the term is used in common parlance--to impose a condition on receipt of federal funds from any program or source because the recipient does not have a viable option to refuse.[49] Even providers of health care services who could forego Medicaid and Medicare transplantation reimbursement, or who could survive non-participation in Medicaid and Medicare altogether, would not be able to risk non-participation in all federal programs.

Despite the coercive potential, courts thus far have refused to invalidate any condition or regulatory program imposed on Medicare or Medicaid providers.[50] Of course, no situation involving heart transplant regulation has yet been argued on this basis; under the Court's current analysis, however, regulation of heart transplantation providers will likely not be invalidated on the ground of coercion.

Coercion, however, is not the only ground upon which health regulation via the spending power can be challenged; the ability of the government to impose conditions on providers may be circumscribed by the notion that such conditions must be reasonably related to the objectives of the particular program to which they are attached. While there is little judicial precedent for such a statement, this limit on the use of the government's conditional spending power appears to be necessitated by the requirements of due process.[51] That is, the condition must be reasonably related to the particular general welfare objective of the funding program to which it is attached, or is at minimum related to some significant policy to which all funding programs should adhere.[52]

If conditions were placed on Medicare reimbursement of heart transplantation that applied only to reimbursed activity, the requirements of due process would probably be met. For example, the government could seek to condition reimbursement for heart transplantation on the provider's adoption of strict patient selection criteria for those patients who will be reimbursed under Medicare, or the meeting of certain quality control factors or other institutional rules.[53] Like existing Medicare and Medicaid conditions on participation, plans of this type would only limit reimbursement under federal programs and would not impose any conditions relating to transplant services funded by non-federal sources. Such regulatory efforts fit neatly into the traditional justification for conditioning receipt of federal monies, and there is an immediate relationship between the program and the condition. Such conditions would be

intended either to limit federal spending incurred under the program or to assure provision of safe and efficacious care and thus would undoubtedly be within constitutional due process limits.[54] All indications are that such conditions will be upheld with a minimum of judicial scrutiny of the condition or its relationship to the program's objectives.[55]

More difficult to establish, however, would be a connection between the condition and the program objective if the objective is to control not only those activities that are funded with federal monies, but those that receive funding from non-federal sources as well. An example would be an attempt under a Medicare reimbursement program to condition participation on compliance with strict patient selection criteria for all patients at the facility, whether eligible for Medicare reimbursement or not. A more extreme example would be an attempt to condition receipt of federal monies on an agreement that a facility not maintain a transplant program at all, even if no reimbursement for transplant activity would be involved. In both of these cases, the condition is far more than a mere specification of when transplant procedures will be reimbursed; the condition could be imposed on activities that are not federally funded. These types of restrictions would not be limited to assuring that reimbursed health care reach appropriate levels of quality and cost-effectiveness; rather, they would be attempts to mandate that providers act in ways that serve the government's broader interests in controlling all transplant costs, achieving efficient allocation of resources, and assuring adequate attention to its notions of safety and equity.

Absent other constitutional bases for challenge,[56] these types of conditions may well be valid. The attempt to control the proliferation of heart transplantation centers, for example, may be enacted to aid in keeping all types of health care affordable--one of the broader objectives of the federal reimbursement programs themselves. Such a condition may, in fact, be related to the more limited goal of containing Medicare costs. As discussed earlier, unchecked diffusion of heart transplantation centers could result in fiscal strains on hospitals, particularly if they cannot be reimbursed for procedures under Medicare. If patients cannot afford the procedure on their own, the costs could be amortized throughout the patient population in the hospital, thus raising the amounts charged for the care of all Medicare and Medicaid patients. Moreover, even truly unrelated conditions attached to federal programs may be constitutional if courts continue to rely on the notion that participation in Medicare and Medicaid is "voluntary." The courts may well take the position that the government is free to attach any condition to a voluntary spending program, related or not, so long as the recipients are free to withdraw or decline participation in the program.

But if individuals can challenge direct regulations that limit their physical access to treatment, can they not similarly challenge limitations accomplished via the spending power? The ability of some individuals to undergo heart transplants may be severely circumscribed if the government seeks, via the spending power, to impose limitations on which patients may be chosen for

unreimbursed transplant procedures, or to limit or regulate non-funded transplant activities. The analysis set out in the abortion funding cases is not dispositive of the possible restriction of access claims, even though the restrictions are accomplished via government spending policy. Unlike the situation in Maher and Harris, these restrictions could limit the access not only of those seeking Medicare reimbursement, but of all individuals who seek heart transplantation.

The Maher court's refusal to find a violation of the petitioner's fundamental right to choose abortion rested on the notion that:[57]

> The Connecticut regulation places no obstacles--absolute or otherwise--in the pregnant woman's path to an abortion . . . it has imposed no restriction on access that was not already there. The indigency that may make it difficult--and in some cases impossible--for some women to have abortions is neither created nor in any way affected by the Connecticut regulation.

Unlike the situation presented in the Maher case, a spending regulation controlling, for example, all patient selection for heart transplantation under programs at hospitals receiving federal monies, or one limiting the number of centers at which heart transplantation could be performed, could create restrictions that would not exist prior to state entry into the field via its regulation.[58] It is arguable, therefore, that the federal government would have to justify such a burdensome regulation by showing a compelling state interest, even though it was accomplished via the spending power. However, the state might argue that it did not create the restrictions on access but, in fact, such restrictions came about through decisions voluntarily undertaken by private health care providers. Since physicians--and

hospitals--are not required to do heart transplantations, the argument may be brought that they may freely decide not to offer those services in order to obtain federal funding. This type of analysis rests again on the notion that conditioning receipt of federal funds to providers is not coercive. However, the coercion cases typically do not involve asserted violation of the rights of third parties not involved in the agreement.

Another possible invalidation of such conditions, or perhaps just another way of stating the above, could come under the doctrine of unconstitutional conditions.[59] The doctrine is based on the general constitutional principle that the government may not accomplish indirectly what it can not do directly. It states that the government may not condition the benefits it offers on the waiver or non-assertion of a constitutional right. By preventing the placement of restrictions on constitutional rights as conditions on government programs, the doctrine prevents the indirect bargaining away of constitutional rights. Generally, however, the doctrine is asserted where the state conditions the grant of a benefit to the individual, rather than where the state conditions a grant to another, in effect limiting the access of the individual and reducing ability to effectuate a protected choice. But if the fundamental right to decide to undergo treatment is recognized, the physician could perhaps assert that the imposition of conditions which limit the ability of all patients to choose to undergo procedures is an unconstitutional interference with the doctor-patient relationship.

E. CONCLUSION

As this section revealed, the right to choose to undergo particular forms of medical treatment has received only limited examination and recognition in the courts. Therefore, much of our analysis is speculative. Yet the following conclusions appear justified in light of current constitutional doctrine. First, no individual is entitled to reimbursement as a matter of right unless the government affirmatively grants it. This conclusion follows from the Maher and McCrae analysis and applies whether or not the right to decide to undergo particular forms of medical treatment is accorded status as a fundamental right. Second, if the right is denied fundamental right status, virtually all regulation will be constitutionally valid, as it will be examined under the rational basis test. The government's ability to regulate via the spending power would be broad as well. Third, if the right is accorded status as an aspect of the constitutionally protected right of privacy, the courts will have to define the contours of the right and the importance of the state interests which will be asserted in favor of regulation.

Our analysis suggested how the courts may view several justifications for regulation of heart transplantation under a fundamental rights analysis. Generally speaking, it is likely that the courts would allow some regulation of this procedure. And although it is difficult and perhaps impossible to assess at this point in time what form of regulation would be constitutionally permissible, it is clear what the type of analysis and some of the factors will be that the courts will most likely consider should a

fundamental rights argument be raised in a challenge to various types of heart transplantation policies. Finally, perhaps the most far reaching implication of this analysis is that it may represent the courts' approach to the regulation of many other innovative biotechnological procedures.

Section 3 - AN ANTITRUST PRIMER: IMPLICATIONS FOR THE REGULATION OF HEART TRANSPLANTATION

A. INTRODUCTION

Application of state and federal antitrust laws in the health care area is a relatively new phenomenon. While this scrutiny of the health professions is relatively new, it is apparent that antitrust law may limit the ability of health care providers to control and coordinate the delivery and financing of specialized medical technologies such as heart transplantation. This paper outlines and briefly analyzes possible antitrust implications of actions undertaken by heart transplant providers and insurers.

Federal antitrust laws embody a belief in the fundamental economic policy that competition is the best allocator of economic resources, the best determiner of prices, and the best promoter of technological and material progress.[1] They are designed to encourage competition on the basis of price, quality and service. Practices that interfere with a potential or current market participant's ability to compete on the merits of the product or service offered are subject to antitrust challenge.[2] Increased emphasis on competition, rather than on government regulation, in health services delivery and financing has caused all activities of health care providers--including delivery of specific services--to be assessed with an eye toward identifying possible anticompetitive practices.

Financing and delivery of highly technological treatments for catastrophic illnesses may raise antitrust concerns beyond those present in most parts of the health care delivery system. Providers

increasingly are turning to cooperation and coordination of highly technological services in order to promote more effective use of resources, to preserve quality of care in complex areas of medical practice, and to facilitate uniform quality-cost tradeoff decisions on behalf of the health care consumer. While the goals may be laudable, such activities may have adverse legal consequences because traditional antitrust analysis rejects the premise that industry-wide groups can serve as unbiased arbiters of price, quantity and quality.[3]

Among the various aspects of the delivery and financing of heart transplantation that may have antitrust implications are such concerns as staffing procedures for cardiological departments. Hospitals' exclusive arrangements with physician-specialists to staff their departments are closing doors to outside providers. While the scope and nature of such arrangements vary widely, one feature is central to them all--the physicians providing the service in question have the right to provide all such service, and the physicians not party to the arrangement are foreclosed from providing any of that service to the contracting health care facility. Because delivery of transplant services may be limited to a few health care facilities at a time when professional interest in the procedure as an accepted method of treatment is increasing, the problem of exclusionary staffing arrangements may be particularly serious for cardiological departments that maintain a heart transplant program.

Another potential area of antitrust concern involves attempts by health care providers to coordinate delivery of services among health care facilities. Renewed efforts to control costs, reduce duplication

of services, and coordinate delivery of transplant services may tempt health care providers to determine among themselves which facilities in any given area will deliver which clinical services, or to allocate territories or patients among transplant facilities. Division along geographic lines may be contemplated, given the concerns over equity of access to transplant services, concentration of services in small areas of the country, and distribution of donors and recipients. Providers could agree that hospital A will perform all transplants on patients living in the New England area, while hospital B will perform all transplants in the New York metropolitan area. While it seems to make logistic and economic sense, such an arrangement closely resembles what is known in antitrust parlance as "market division". Allocation or division of markets among two or more actual or potential competitors has been held to be per se illegal under traditional antitrust analysis, even where no collateral attempt to fix or control prices is involved.[4]

Specialty certification is also a likely area of antitrust concern. Due to the highly technological nature of transplantation, implementation by medical communities of formal certification processes for transplant service personnel may be in the offing. However, specialty certification has been the subject of antitrust dialogue in the legal community because of its conflicting pro- and anticompetitive effects upon the health care marketplace.

These are several examples of possible antitrust issues connected with heart transplantation. Before we identify and present for further study other specific practices, we will outline the fundamentals of

antitrust law and their applicability to heart transplantation practices. Because of the vast scope of this undertaking we shall not attempt to analyze in depth the issues and practices that we identify as potential trouble spots.

B. THE BASIC ANTITRUST STATUTES

The principle antitrust statutes are Sections 1 and 2 of the Sherman Act, the Federal Trade Commission Act, and the Clayton Act. The most important of these, the Sherman Act, has two very brief and somewhat cryptic provisions. Section 1 of the Sherman Act broadly condemns contracts, combinations and conspiracies in restraint of trade or interstate commerce.[5] Section 2 of the Sherman Act deals with monopolization, attempts to monopolize, and conspiracies to monopolize.[6] The Federal Trade Commission Act, Section 5,[7] has two types of prohibitions. It prohibits both "unfair methods of competition,"[8] and "unfair or deceptive acts or practices."[9] The Clayton Act supplements the Sherman Act by naming and prohibiting certain specific types of practices, such as illegal mergers and price discrimination.[10]

1. SECTION 1 OF THE SHERMAN ACT

Section 1 of the Sherman Act (Sherman 1) condemns contracts, combinations, and conspiracies in restraint of trade or interstate commerce. While the Sherman Act literally prohibits every contract in restraint of trade, it is invoked only against those agreements that unreasonably restrain trade[11] a concession to the obvious fact that all contracts restrain trade to some extent but that commerce cannot

function without them. Two prerequisites govern the application of Sherman 1. First, two or more parties must be involved in the restraint; Sherman 1 cannot be applied to single firm behavior. Second, an agreement must have been made -- the parties must have decided upon a particular mutual course of conduct.

Judicial consideration of Sherman Act prohibitions has resulted in two broad classes of offenses: rule of reason and per se. In rule of reason cases, courts recognize that the type of restraint involved may have both pro- and anticompetitive aspects that must be balanced before a determination of legality or illegality is made. Rule of reason requires a full scale assessment of the challenged activity in terms of the nature of the restraint, the power of the market participants, the purpose of restraint, and its effects on competition. Business rationales for the arrangements are considered, but the challenger is allowed to show that less restrictive alternatives are available to obtain the desired business purpose.[12]

An important consideration in rule of reason cases is the market power[13] of the groups responsible for the anticompetitive practice. Unlike a Section 2 monopolization offense, monopoly power[14] is not a prerequisite in this case -- defendants need only substantial economic power in the relevant market.[15]

The Supreme Court has taken the position that Congressional enactment of the Sherman Act forecloses the pursuit of anticompetitive practices for good motives. The Court's opinion in National Society of Professional Engineers v. United States[16] sets out the permissible parameters of inquiry for rule of reason analysis. Its

language limits the inquiry to the impact of the challenged practice on competition; no "social benefit" justifications are considered.

The courts have concluded that some practices could never be justified because they nearly always restrained trade. These offenses are labelled "per se". If an activity fits within a per se category, it is conclusively presumed to be anticompetitive. Once the plaintiff proves that the defendant committed the act, the court will not permit the defendant to justify it on any grounds.

The courts have developed different types of rule of reason and per se offenses, which are informally classified into "horizontal" and "vertical" categories. Horizontal offenses involve an agreement or conspiracy among competitors; vertical offenses involve buyers and sellers. Some relevant types of offenses are briefly outlined below.

a. Horizontal Restraints. Horizontal restraints are activities that result from concerted or collusive activities between competitors. Such activities that restrain competition are prohibited by Sherman 1 (by FTCA 5). A finding of an illegal contract or conspiracy does not require formal agreement. Rather, an unlawful agreement or conspiracy is usually demonstrated by circumstantial evidence. There are four main types of horizontal restraints: price fixing, concerted refusals to deal, market division, and data dissemination. Each is outlined below.

1) Price fixing. Agreements among competitors relating in any way to price, even agreements that only indirectly affect price, are per se violations of the Sherman Act.

2) Concerted refusals to deal. A concerted refusal to deal is an agreement between competitors to refuse to do business with another.[18]

3) Division of markets between competitors. Under traditional antitrust analysis involving business activities, allocation or division of markets among two or more actual or potential competitors is per se illegal, even where no price-fixing is involved.[19] Market division can occur in several ways, either along territorial or product lines.[20]

4) Data dissemination. The exchange of information among competitors has been the target of considerable antitrust scrutiny. Such information exchange is often accomplished through "trade associations" that are combinations of their members and therefore subject to Sherman 1 scrutiny.[21]

b. Vertical Restraints. Vertical restraints arise from agreements between buyers and sellers of services or goods. Such agreements may restrain trade in violation of Sherman 1, as with as Sherman 2, Clayton 3, and FTCA 5 (explained below).

1) Resale price maintenance. One common violation involving buyers and sellers is "resale price maintenance", the vertical companion to horizontal price fixing. Resale price maintenance involves agreements between buyers and sellers to fix the price at which the buyer will resell the product. Such agreements are per se unlawful.[22]

2) Concerted refusals to deal. The prohibition of concerted refusals to deal also applies to agreements between a seller and its buyers to exclude other sellers or buyers.

3) Tying arrangements. In a tying arrangement one party will sell a product or service only if the buyer agrees to purchase a second product or service as well (the tied service). Tying arrangements generally receive per se treatment where the seller has sufficient economic power in the tying product/service market to appreciably restrain trade in the tied product/service market. Tying arrangements may be found to be justified under very limited circumstances.[23]

4) Exclusive dealing. An exclusive dealing arrangement is one in which a seller requires an agreement that a buyer will buy only from that supplier. To be unlawful, such a contract must be more than simply a contract to buy goods -- there must also be a substantial adverse effect on the competitive opportunities of other firms to supply the ultimate consumer. One such agreement is the requirements contract, involving a buyer's agreement to purchase all his or her needs for certain goods or services for a specified period of time from the seller. The Court generally uses a rule of reason analysis in this area, although the tests put forth in the cases are conflicting.[24]

Because labelling a restraint a per se violation carries a presumption of illegality, the main issue in an antitrust case often is whether an activity should be analyzed as a per se or a rule of reason restraint. It is usually preferable for the plaintiff to plead

and establish a per se offense because it truncates the trial and allows the plaintiff to avoid responding in court to the defendant's attempted justification for his or her actions. Beyond the per se offenses listed above, the courts do not agree on other types of arrangements that merit per se treatment. They often attempt to distinguish an arrangement that appears to fall in a per se category if they feel it is not perniciously anticompetitive because they are reluctant to introduce the per se presumption of illegality.

2. SECTION 2 OF THE SHERMAN ACT

Section 2 of the Sherman Act (Sherman 2) condemns monopolization, attempts to monopolize, and conspiracies to monopolize any part of interstate commerce.[25] In contrast to Sherman 1, Sherman 2 can be violated by a single party.

There are two elements to a Sherman 2 monopolization offense. First, the plaintiff must show that the defendant has attained "monopoly power" in a "relevant market". Second, the plaintiff must show that the defendant has engaged in "monopolizing conduct".

a. Monopoly Power. "Monopoly power" is defined as the ability to control price or to restrict competition where desired.[26] The critical element is not whether that monopoly power is actually used to exclude competitors but whether such power exists.[27]

b. Relevant Product Market. The relevant product market determination inquires into products or services that are reasonably acceptable substitutes for the products or services of the defendant. The court generally defines the relevant product market expansively,

and will include all goods or services that are reasonably interchangeable with the defendant's goods or services.[28]

c. Relevant Geographic Market. The determination of the relevant geographic market involves transaction costs--one looks toward barriers that limit firms sales efforts to certain areas, for instance, governmentally imposed restrictions (as in the banking industry), transportation costs, and customer inconvenience. As in the relevant product market determination, the wider the definition of geographic market, the more difficult it will be to show monopoly power.

d. Percentage of Market Control. The remaining question concerns the percentage of market control that is necessary to establish monopoly power. Although the courts have not established a decisive figure, the cases do establish a range of possibilities that identify a market share as monopolistic.[29] In general, the defendant's market power must be enough to restrict entry, supply, or price.

e. Monopolizing Conduct. Mere possession of monopoly power does not establish a Sherman 2 violation; monopolizing conduct must also be demonstrated. Monopolizing conduct is defined as intentional activity that tends to exclude competitors and is not necessary for the purpose of socially approved competition on the merits. However, it is to be distinguished from growth or development as a consequence of a superior product, business acumen, or historical accident.[30]

f. Attempt and Conspiracy to Monopolize Offenses. When actual monopolization cannot be proven, plaintiffs may try to

establish the existence of a conspiracy or an attempt to monopolize under Section 2 of the Sherman Act. A conspiracy offense may be demonstrated by: (1) an agreement entered into by two or more parties with specific intent to achieve a monopoly, and (2) commission of an overt act in furtherance of the conspiracy. While some doubt exists about the precise elements of the attempt to monopolize offense, it appears that one must show (1) conduct undertaken with specific intent to obtain a monopoly, and (2) a dangerous probability of success.[31]

3. FEDERAL TRADE COMMISSION ACT

Another relevant statute is the Federal Trade Commission Act.[32] Section 5 of the Act (FTCA 5) contains two types of prohibitions. First, it prohibits "unfair methods of competition". This section gives the Federal Trade Commission (FTC) jurisdiction over all offenses that violate the Sherman and Clayton Acts, and allows it to challenge restraints that technically do not violate either Act but are contrary to the "spirit of the antitrust laws."[33]

In addition, the Act prohibits all practices that may be deemed unfair to consumers.[34] Unlike the Sherman and Clayton Acts, which turn to the court to determine legality, the FTC defines unfair methods of competition and unfair or deceptive acts or practices.

The Federal Trade Commission Act has more limited application, particularly to heart transplantation, than either the Sherman or Clayton Acts, because it is enforceable only by the FTC. Neither the Department of Justice nor private litigants can bring suit under FTCA 5 and FTCA 5 generally does not apply to non-profit

entities unless they are "organized to carry on business for [their own] profit or for that of their members."[34]

4. CLAYTON ACT

The Clayton Act, the third main antitrust act, was enacted to supplement the Sherman Act by naming and prohibiting specific types of practices, such as illegal mergers, to which the courts had not yet applied the Sherman Act. The Clayton Act includes a section referred to as the Robinson-Patman Act that prohibits price discrimination.[36] Section 3 of the Clayton Act concerns exclusive dealing, requirements contracts, and tying arrangements, all of which have appeared in health care antitrust cases. However, these offenses in the health care area typically are charged under the Sherman Act, because the Clayton Act applies only to the sale of good or commodities.

With the general framework of antitrust analysis in mind, we now apply the statutes to health care and heart transplantation.

C. ANTITRUST AND HEALTH CARE: EROSION OF TRADITIONAL DEFENSES

Recent doctrinal developments have rendered the antitrust laws important in the health care field. For years, their application to health care providers was limited by a number of defenses that have been greatly eroded by recent Supreme Court decisions. As a result, two points are now certain: (1) health care providers are not exempt from antitrust scrutiny, and (2) the activities of health care providers will be actively scrutinized by the courts to screen out impediments to the competitive process. The recency of these

decisions and the often fact-sensitive nature of antitrust analysis leave unclear the extent to which health care providers will be treated differently from other industries.

The first defense raised against application of antitrust laws to the professions was that they were "professional" rather than "commercial" and thus exempt under the antitrust laws. The Supreme Court has now rejected any notion of a blanket exemption for the "learned professions."[37] However the Court has periodically held out the possibility that professional services would be treated differently from other industries.[38]

Nevertheless, each successive statement of this possibility by the Court has been more narrowly phrased than its predecessor.[39] Moreover, the Court has yet to decide a case that limits the reach of antitrust principles into a profession's self regulatory domain.[40] It remains to be seen how the Supreme Court will finally treat the professions and whether practices associated with health care will be found to be entitled to any sort of special treatment.

The second traditional defense against application of federal antitrust laws to the professions was that their practice was often local and thus lacked the effect on interstate commerce necessary to federal antitrust offenses. Recent Supreme Court decisions, however, indicate that the interstate commerce defense will not have broad application in health care cases.[41]

The third traditional defense arose from antitrust laws' general application only to the anticompetitive behavior of private parties directed at other private parties. Restrictive practices associated

with delivery of services by the learned professions often are mandated and/or loosely regulated by the states. It was argued that such "state action" prevented application of the antitrust laws to the challenged professional practices.[42] But recent Supreme Court cases, held that mere acquiescence of the state in such decisions and practices is not enough to warrant application of the state action defense.[43]

The erosion of these defenses has led to current challenges of many potentially anticompetitive activities in the health care. The next section discusses the most common types of challenge and their particular importance to activities in the heart transplant field. We then return to a discussion of possible defenses to antitrust actions involving health care activities, and the current doctrine surrounding application of per se and rule of reason analysis to health care antitrust cases.

D. THE ANTITRUST LAWS IN HEALTH CARE AND HEART TRANSPLANTATION

Many health care activities resemble practices that have been challenged under the antitrust laws in typical commercial settings.

1. DIVISION OF MARKETS BETWEEN COMPETITORS

As stated earlier, allocation or division of markets along product or geographic lines has been held to be a per se offense, even when no collateral attempt to fix prices was involved.[44] Market division arrangements may become increasingly common in health care, particularly in areas such as heart transplant action. All one has to do, as Proger has pointed out, is to think of a hospital and the

various types of services that hospitals provide.[45] One can envision an agreement among, let us say, Boston area hospitals, that one will handle severe burn therapy, another intensive neonatal care, and another heart transplantation. Justifications for such an arrangement could include improving the efficiency of health services delivery through economies of scale, reductions in the duplication of services and improving the quality, comprehensiveness, and continuity of patient care.

It is equally likely that geographic division will be contemplated with respect to heart transplantation services. Thus, providers could agree that hospital A will perform all transplants on patients living in the New England area, while hospital B will perform all transplants in the New York metropolitan area.

Such an arrangement could well be viewed favorably in the organ transplant community. Indeed, several key individuals may be thinking along these lines already.[46] For example, Francis Moore, a pioneer in transplant surgery, bemoaned the fact that the Boston area lacked a heart transplant program and stated his support for regional transplant centers in a letter to the New England Journal of Medicine.[47] Moore[48] has since restated his position, again recommending that heart transplantation be undertaken at selected institutions, regardless of cost. He states that:

> (t)he distribution of donors, as well as the presumably equivalent distribution of potential recipients, however, mandates the wider availability of cardiac transplantation.

Moore recommends that centers be distributed to coincide approximately with the census districts or Army Corps areas. He further notes that "(t)here should be nine or ten centers in this country with the teams, cardiologic backup, cadaver donor procurement capability and experience, and the cardiac surgical team expertise to make cardiac transplantation available to those who need it."[49] Copeland and Stinson[50] have also suggested that heart transplantation should be performed on a restricted basis at selected centers.

These quotes are not intended to suggest that members of the transplant community are currently involved in arrangements that violate antitrust laws. Nevertheless, territorial or service division arrangements among hospitals could raise significant antitrust challenges, regardless of their apparent economic and logistical soundness. Havighurst has noted that antitrust laws do not allow anticompetitive collective actions to be justified on the basis that competition would be undesirable. Instead, as he notes, the law "embraces the conclusive presumption that competition is always preferable unless Congress has declared otherwise".[51] Complicating the analysis is the fact that the National Health Planning and Resources Development Act and local and state health planning agencies actually may encourage such arrangements. Moreover, courts may be reluctant to apply per se rules to the health care marketplace outside of the area of price-fixing, and may carefully examine such arrangements before pronouncing on their legality.

2. EXCLUSIVE STAFFING ARRANGEMENTS

More hospitals are utilizing exclusive arrangements with physician specialists to staff departments because the hospital can use them on an "as needed" basis, and because it may be economically more sound for the hospital's. Physicians under such arrangements provide all of the particular types of services covered by the arrangement, while physicians not party to the arrangement cannot provide any of the services covered. The opportunities for practice for those without such privileges will be limited by the closure of many hospital facilities to their use. The exclusionary aspect of these arrangements has spawned a series of antitrust challenges. While many specialties are offered under exclusive arrangements,[52] those most relevant to our purpose are exclusive arrangements for cardiac surgery[53] and for specific cardiological procedures.[54] Several such arrangements may have already led to antitrust challenge.

The complex and technologically innovative nature of the technique makes heart transplantation practice a likely candidate for exclusive hospital staffing arrangements. The currently limited number of centers performing heart transplantation, and possible future regionalization of transplant services, may mean that the number of cardiac surgeons and cardiologists with heart transplantation skills soon will exceed the number of openings for physicians at hospitals with transplant facilities. Excluded physicians may allege that denials of staff privileges were unrelated to their qualifications, and were based on the hospital's notion of the best

size for its heart transplant staff, in restraint of trade and therefore illegal.

Antitrust challenges to exclusive arrangements have taken a number of different forms. Because it is difficult to prove anticompetitive effects under the rule of reason, many recent cases have alleged per se violations of the antitrust laws.[55] However, some analysts argue that hospital-physician exclusive arrangements are analogous to exclusive distributorship agreements in a commercial setting that typically receive rule of reason rather than per se treatment.[56]

3. SPECIALTY CERTIFICATION

As medical science becomes more technologically complex, concern that providers be competent in an area of practice has taken on increasing importance. Such concerns have spurred the medical community to implement formal certification programs in many areas of medical practice. Heart transplantation may be a likely area for specialty certification because it involves mastery of highly complex areas of practice, not only for transplant surgeons, but for nurses, cardiologists, anethesiologists and others.[57]

Specialty certification is an area in which private restraints may be sought and challenged under the antitrust laws. Clark Havighurst has noted that while certification recommends itself as an information service to consumers and others, antitrust problems may exist concerning the objectivity and fairness of standards and their application, the division of markets among certified categories, grandfathering when standards are raised, and the freedom of

alternative certification agencies to enter the market and provide alternative sources of information. Moreover, the system may be challenged as too restrictive if the independent decision makers rely on misleading certification information, or (as in the case of hospitals), are dominated by certified specialists, each with a stake in promoting certification as a prerequisite to hospital use.[58] If transplant centers are regionalized or are otherwise limited, and the number of health care professionals desiring to work in the field exceeds the number of positions open, high certification standards could lead to legal challenges.

4. HEALTH CARE FINANCING AND THE ANTITRUST LAWS

Diffusion of heart transplantation and other technologically complex forms of treatment for catastrophic diseases has been accompanied by continuing debates over the high cost of such treatment, and medical technology's contribution to the escalation of health care costs in general. Health care expenses have continued to rise despite a plethora of regulatory controls aimed at cost containment.

In recent years, attention has turned from the regulatory approach to health care cost containment toward means of stimulating competition among health care providers. One suggestion is to introduce economizing innovations in the organization and administration of public and private plans for financing health care.[59] Redesign of current open-ended, nearly all-inclusive health care financing may allow cost-conscious consumers to purchase health care plans in a competitive market, and transmit their concerns about

health care costs to insurers, who will in turn transmit them to providers.[60]

The emphasis on innovation in health care financing directly concerns heart transplantation because it is a prime candidate for health insurance coverage limitations or exclusions. This is especially true given the current perception of heart transplantation as an "quasi experimental" and very costly form of treatment.

Cost control mechanisms that could affect heart transplantation may assume many different forms. in private insurance plans Two likely forms are explicit exclusions from coverage, and closed panel or preferred provider coverage.[61] As part of an overall cost containment program, insurers may decide to exclude coverage for certain services, or they could limit coverage by imposing copayments, deductibles, and limits on what they will pay in particular circumstances, or in the aggregate. If such strategies could be adopted at a reasonable cost, consumers could find the correspondingly lower premiums to be advantageous despite the greater exposure to uncovered risks. An alternative approach would be to limit coverage to services obtained from specified providers, who are perceived to render services more efficiently and at a lower cost, in order to enable the plan to effectively limit its coverage of questionable items without explicitly excluding heart transplantation or other services. Another alternative would be to pay for the services of providers deemed less efficient on a less advantageous basis by requiring a larger copayment from subscribers.

It appears increasingly likely that these or other cost containment measures may be adopted to curb health care expenditures, and to foster competition and efficient resource allocation. Many arguments can be--and have been--raised for and against various strategies.[62] For our purposes, it is sufficient to note that similar developments affecting payment for transplantation may lead to antitrust problems if, as has happened when these innovations have been introduced in other parts of the health care arena, the medical profession resists them through informal collective action and formal legal challenge.

a. Anticompetitive Provider Behavior. Havighurst has noted that because of their historical professional autonomy physicians often respond to what they perceive as outside interference in their affairs by taking collective action through their local, state, and national professional associations, through hospital staff organizations, and through less formal mechanisms.[63] These professional groups must be prepared to defend their actions because they may be viewed as combinations of competitors under federal and state antitrust laws.

While professional groups may be allowed more leeway than industrial trade associations, some practices engaged in by providers-such as opposition to financing arrangements, implementation of their own fee schedule and restricting dissemination of data or information--may be closely scrutinized under antitrust laws.[64]

1) Opposition to financing arrangements. A practice likely to be condemned is a collective decision by physicians to

cancel participation agreements with insurer unless it agrees to change its policies concerning exclusion or limitation of reimbursement for procedures such as transplantation. A medical society's resolution condemning an insurer's adoption of a particular policy, coupled with a call for members to stop or change their dealings with the "errant" insurer might also attract antitrust attention.[65] Recently, the FTC recently condemned several such actions that were directed against insurers. However, the Commissioners do not agree on whether to apply per se or rule of reason analysis.[66]

Health care providers' attempts to influence third party insurers will not always be illegal. There must be concerted action on the part of the providers.[67] A physician or health care provider who, as an individual, believes that it is not advantageous to deal with an insurer may refuse to do so. What will lead to legal challenge is combination with other providers in a concerted plan toboycott an insurer. Second, rule of reason analysis may be applied and the action upheld if the courts or the Commissioners (in an FTC action) judge the pro-competitive aspects to outweigh the anticompetitive aspects.

2) Implementation of fee schedules. One of the oldest Sherman Act offenses is price fixing. As the Supreme Court has made clear in Arizona v. Maricopa County Medical Society,[68] the per se rule against price fixing will be applied in the health care area.

While a narrow decision,[69] Maricopa raises questions about other cooperative activities aimed at cost containment. There

undoubtedly will be more litigation involving price-fixing charges as various forms of fee scheduling and other organized cost containment measures are challenged.[70]

3) Data dissemination. Earlier we noted that the exchange of information among competitors may raise issues of antitrust liability. Medical societies and less formal groups of health care providers often share information via proposals, resolutions, and opinions in a variety of professional concerns. Information sharing about donor availability, tissue types, donees and their location is particularly prevalent in transplantation. Transplantation providers may seek information about the quality of organs procured at a particular procurement facility or wish to exchange information about prices charged for various services.

The free exchange of information about health care innovation is vital to the development of medical service and health care. However, in some instances, information sharing may be viewed as impeding competition and could be actively scrutinized under the antitrust laws. For example, a medical society's condemnation of a health insurer's adoption of a particular cost containment practice might lead individual physicians to refuse to deal with that insurer and thereby impede cost containment efforts. Or physicians might circulate an advisory fee schedule which could lead to antitrust challenge even if no medical society enforces it. The parameters of anticompetitive data dissemination in health care have not yet been seriously assessed.

b. Anticompetitive Insurer Behavior. The rising cost of health care is an incentive for health insurers to develop health insurance plans that allow greater control over the cost and quality of services rendered to insureds. While these plans may take many forms, two possible forms--explicit coverage exclusions or limitations, and preferred or limited provider arrangements--could lead to formal legal resistance because of adverse effects on members of the health care professions. Recent cases involving antitrust law and health care illustrate the probable analysis that would be applied to insurer practices that could affect payment for heart transplantation. Before discussing that analysis, however, this section discusses of the McCarran-Ferguson Act exemption from antitrust scrutiny of activities within the "business of insurance" and the changes recent Supreme Court decisions have made in the effect of the Act.

1) The McCarran-Ferguson exemption. The McCarran-Ferguson Act[71] exempts from antitrust scrutiny the "business of insurance" to the extent that it is regulated by state law, provided that the challenged activities do not involve boycott, coercion or intimidation.[72] Many activities of third party insurers appeared exempt under the Act until three recent Supreme Court decisions interpreted this exemption narrowly and thereby allowed challenges of insurer practices.

2) Participating provider agreements. Health care providers challenged insurers' cost containment arrangements under antitrust principles. If insurers limit reimbursement to providers who meet contractual specifications or to a set number of providers

who meet certain criteria, they may place the excluded provider at a competitive disadvantage, and place themselves in a position to control entry by new providers. One can clearly envision preferred provider arrangements in heart transplantation cases.

Most case law involving exclusions or limitations on who may provide services for insureds has involved Blue Cross and Blue Shield (BCBS) programs. Blue Cross and Blue Shield utilize two types of contracts--subscriber contracts and participating provider agreements (PPAs).[73]

The BCBS subscriber generally is free to choose either a participating or a non-participating provider. However, if he or she deals with a participating provider, BCBS will make payment directly to the provider and the insured will be billed only for uncovered amounts. If the insured utilizes a non-participating provider, he or she must first pay the bill and then seek reimbursement from BCBS. BCBS generally pays less to an insured using non-participating providers than it pays directly to a participating provider.

BCBS need not award participating provider status to all who request it, and may set terms to which the provider does not wish to agree. Because denial of preferred provider status can place the excluded provider at a competitive disadvantage, PPAs have been at the center of several recent antitrust actions. Although the recent case law case indicates that PPAs do not fall within the business of insurance exemption, these cases have upheld PPAs against antitrust challenge.[74]

Medical Arts Pharmacy of Stamford, Inc. v. Blue Cross and Blue Shield of Connecticut, Inc.[75] involved a challenge to a PPA for a maximum billable amount method of reimbursement offered by BCBS to all Connecticut pharmacists. The court found that there was no resale of anything, and hence no anticompetitive effect.

Sausalito Pharmacy,[76] like Medical Arts, involved a prepaid drug prescription program under which each participating pharmacy would provide prescription drugs at stipulated prices that were alleged to be less than current charges of the pharmacies to uninsured customers.[77] The court held that the arrangement did not violate Section 1 of the Sherman Act, because the insurers, not the insured, were purchasers of the drugs.[78]

The court then turned to the question of whether the agreements were unreasonable vertical restraints of trade, and held that contracts between purchasers and sellers "do not impermissibly restrain trade unless there is some effect on price formation other than the terms of the contract itself."[79]

Another recent opinion involving PPAs is Glen Eden Hospital Inc. v. Blue Cross and Blue Shield of Michigan.[80] Glen Eden Hospital, a for-profit private psychiatric hospital, sued BCBS on three counts[81] The court found no violation of Sherman 1 in the Count I claims, because plaintiff could prove no conspiracy.[82] Absent proof of some boycott or price fixing conspiracy, agreements determining the amount of reimbursement do not constitute vertical restraints of trade under either a rule of reason or per se analysis.[83] The Count II claims alleging Sherman 2 violations were

rejected because there was no showing of unlawful acquisition and use of monopoly power.[84] The court therefore awarded summary judgment to BCBS.

The Michigan Court of Appeals recently decided that a moratorium by BCBS of Michigan on approving any new psychiatric clinics for participation in its reimbursement scheme did not run afoul of the state antitrust law because there was no showing of concerted action to restrain trade.[85] The court distinguished Virginia Academy of Clinical Psychologists v. Blue Shield of Virginia[86] because there was no evidence of provider control of the insurer.

If third party payers adopt a preferred provider approach with respect to heart transplantation, or otherwise limit provider participation under their plans, they may be in a position to control entry by new transplantation centers and give the selected providers competitive advantages in the delivery of transplant services. Such insurer practices could lead to antitrust challenges similar to those outlined above.

3) Peer review. Many third party insurers engage in some form of utilization or peer review to determine if a provider has rendered unnecessary or inappropriate medical care. The review generally examines such factors as length of stay, ancillary charges, and analyses of patterns and profiles of customary treatment for particular illnesses. Insurers who cover transplant services may subject providers to particularly rigorous utilization review, because of the novelty of the procedure, the high costs involved, the

variation in charges between transplant centers,[87] the need for selectivity to assure good patient survival rates, and perhaps out of concern for efficient use of scarce donor organs and other resources. Thus, antitrust problems surrounding the peer review process may affect coverage of heart transplantation services as well as more common forms of treatment.

Peer review can affect health care prices and the status of health care professionals. If a peer review committee finds the prices of a provider to be unreasonable, or the service unnecessary or inappropriate, the insurer may not reimburse for the treatment. Over a period of time, peer review may cause providers who have been denied reimbursement to lower their prices or to select treatment more carefully for their patients.

Because peer review involves a cooperative effort and may have an effect on prices, it runs the risk of antitrust challenge[88] particularly since the Supreme Court has held that peer review was not part of the business of insurance and not exempt from antitrust scrutiny.[89]

E. ANTITRUST ISSUES IN ORGAN PROCUREMENT

Transplantable organs are a relatively scarce commodity. As a result, transplant programs often work together to increase the general supply of organs and to assure their own supply through joint organ procurement activity. Antitrust issues may develop if transplantation providers jointly refuse to deal with certain organ procurement agencies (OPA's) that engage in activities or practices

that providers do not like. Restrictions on who may receive organs from any OPA, and exclusive dealing arrangements may also exist in organ procurement activities. Since more information is known about the procurement network for kidneys, it, rather than the heart procurement network, will illustrate potential application of the antitrust laws in this area.

There are approximately 152 kidney transplantation providers in the U.S.,[90] of which about three-quarters run their own organ procurement agencies (OPAs), (the remainder depend on Independent Organ Procurement Agencies (IOPAs)). All OPAs are non-profit agencies, either directly incorporated as such, or operating as a division of a non-profit hospital.[91]

In most places, organ procurement was begun on an ad hoc basis by the physicians involved in transplantation, who used personal contacts to obtain assistance and referrals. Formal organ procurement agencies usually evolved when the physicians found the burden of the work too onerous and the yield of organs too small. Some IOPAs formed as a way of resolving interhospital competition in cities with several transplantation hospitals; hospitals felt the need for more effective procurement, but were unwilling to grant primacy to any other hospital, so a neutral organization was established.

Hospital-based procurement agencies are structurally ancillary to the transplant team. While most hospital-based agencies operate in a single hospital, or, at most, in several hospitals in a single city, many IOPAs are regional in scope. Although IOPAs represent only 18%

of the nation's OPAs, they obtain over 40% of the nation's transplantable kidneys.

IOPAs generally share a common broad organizational structure. They are incorporated non-profit organizations, with a board of directors made up almost entirely of physicians representing the transplant hospitals in the region.

We now turn to the legal issues raised by the activities of OPAs. As stated, all OPAs are non-profit organizations but antitrust laws, as a general rule, do not differentiate between profit and not-for-profit entities -- non-profit entities also can engage in competition with each other. While many OPAs are shared service organizations (i.e., entities organized and operated to perform, on a centralized basis, one or more services for two or more health care providers), the fact that they originated to obtain economies of scale and to reduce costs (and perhaps increase the supply of organs) does not immunize their acts from antitrust scrutiny.[92] However, the FTC may not have jurisdiction over OPAs because its jurisdiction is limited to entities" organized to carry on business for (their) own profit or for that of (their) members;"[93] though it has obtained jurisdiction over associations "whose activities engender a pecuniary benefit to its members if that activity is a substantial part of the total activities of the organization rather than merely incidental to some non-commercial activity."[94] And even if the FTC does not have jurisdiction, the Antitrust Division of the Department of Justice and private treble damage litigants may bring suit under the Sherman Act.[95]

1. SUBSTANTIVE LEGAL ISSUES IN ORGAN PROCUREMENT

a. Concerted Refusals to Deal. A vital part of organ procurement activity is sharing--an organ that cannot be used locally is generally sent elsewhere,[96] but a decision must then be made as to which program or agency will receive it.

Many constraints influence who will get the organ. Time is a factor because successful transplantation depends on quick removal and implantation of the organ. OPAs therefore prefer to export organs to nearby colleagues, and to centers in major air traffic areas. Another important factor, however, is the reputation of the transplant facility.[97] One can imagine a reluctance on the part of OPAs to deal with others associated with transplant teams with poor reputations, or indeed, a reluctance on the part of transplant teams to deal with certain OPAs. But an organized decision to refuse to deal with a particular OPA or transplant team could lead to antitrust challenge.

Though not authoritative, a case involving a similar situation was decided in 1966 by the FTC in Community Blood Bank, Inc.[98] The FTC held that medical and hospital interests had unlawfully boycotted two commercial blood banks. The concerted refusal to deal with the bank apparently arose out of the respondents' objection to "trafficking in human blood" and a professional (though undocumented) concern with the quality of blood supplied. The Commissioners held that the concerted activity of the respondents hindered the development of the commercial banks, and that no "group of private citizens, no matter how public spirited or altruistically

motivated, may . . . relegate to themselves the . . . governmental function of determining the standards . . . applied [to] the interstate operation of blood banks".[99] They also stated:

> . . . As long as commercial blood banks are authorized by law, they are entitled to protection from such a combination or conspiracy, whether inspired by a good faith, but overzealous effort to insure the success of a community-sponsored bank, a desire to impose more rigid standards upon blood banks than those now existing, or a belief that human blood should not be bought and sold. Nor may they take such action because they hold the opinion that the buying and selling of blood is morally wrong.[100]

The sale of organs has recently attracted much attention there are no direct legal barriers to buying and selling organs.[101] Such commercial activity in organ procurement may engender the same response from the transplant community as did the sale of blood in the Community Blood Bank case. And, if the analysis in that case is followed, any organized attempt to drive commercial organ procurement agencies out of business, for any motive, could lead to antitrust challenge.

b. Restrictions on Membership in IOPAs. If an economic benefit derives from belonging to a group, and that group refuses to admit a competitor that cannot, by itself, obtain that economic benefit, denying membership may constitute an illegal group boycott.[102] The reasonableness of the purpose for the boycott or the methods used are generally not relevant.[103]

Suppose that all transplant facilities in the East formed an IOPA/shared organ service. After its formation, X hospital starts a transplant program. Access to the IOPA will allow X to operate more

effectively by enabling it to obtain more organs that more suitably match its patients, and would therefore allow it to transplant more patients than if it relied on its own retrieval program.. The IOPA members, either because they feel there are too many transplant programs in the East already, or because they doubt the quality of services provided at X, refuse to allow X to join the IOPA. Such actions could result in an antitrust claim of concertedly refusing to deal.

Some restrictions on membership are legitimate, i.e., restrictions mandated or compelled by state or federal law, and reasonable restrictions based upon physical limitations. A restriction requiring members to be located in a given geographic area may be reasonable if the boundaries are based upon the area that the IOPA can effectively service, and if the boundaries are not drawn artificially to exclude a specific transplant provider.

F. SPECIAL TREATMENT FOR THE HEALTH CARE PROFESSIONS

It is difficult to predict accurately the antitrust issues that may arise in the financing and delivery of heart transplant services. It is equally unclear how those issues might be analyzed if challenged. We have noted that the Supreme Court has refused to exempt the learned professions from antitrust laws, but has maintained that there may be instances in which the professions will be treated differently from general commercial actors. In Goldfarb v. Virginia State Bar the Supreme Court cautioned that:

> The fact that a restraint operates upon a profession as distinguished from a business is, of course, relevant in determining whether that particular restraint violates the Sherman Act . . . The public service aspects, and other features of the professions, which could properly be viewed as a violation of the Sherman Act in another context, may be treated differently.[104]

Yet in National Society of Professional Engineers v. United States,[105] yet, the Court specifically held that no analysis under the antitrust laws, including those involving the professions, would include consideration of public safety or social benefit goals. The sole purpose of judicial analysis is to "form an opinion about the competitive significance of the restraint . . . not to decide whether a policy favoring competition is in the public interest, or in the interest of the members of an industry."[106]

As in Goldfarb, however, the Court inserted a cautionary note that is still adhered to, i.e., the view that "by their nature, professional features of the services may differ significantly from other business services and accordingly, the nature of competition in such services may vary."[107]

While the Supreme Court has given little indication of what type of special treatment should be applied to the professions, the lower courts and the FTC have been handling health care cases in ways that indicate clear reluctance to analyze health care activities under ordinary antitrust categories of offenses.

This situation may or may not change due to the recent Supreme Court decision in Arizona v. Maricopa County Medical Society,[108] although Maricopa, like Goldfarb, provides little guidance for health

care cases that do not involve overt price-fixing. Maricopa dealt only with the question of whether the fee schedule involved should be analyzed under the rule of reason or per se approach, and did not indicate whether allegedly anticompetitive agreements that do not directly affect price will be accorded per se treatment. While any agreement among competitors provides a target for antitrust plaintiffs, Maricopa does not make every such contract per se illegal. Nor does it suggest the types of agreements that would be illegal under the rule of reason because they fall within the Goldfarb/Professional Engineers exception. Thus the Maricopa opinion represents no change in the attitude of courts toward application of the antitrust laws to the health care industry.

Post-Maricopa trial courts will probably still be reluctant to apply per se rules in cases involving practices other than price-fixing by health care providers. And their unfamiliarity with health care economics may lead them to require plaintiffs to prove the anticompetitive effects of the challenged practice at full trial or to engage in an abbreviated examination of the competitive effects of the challenged arrangement before applying the per se label.[109]

Ready examples of refusal to apply the per se label are the FTC's decisions, In re Michigan State Medical Society,[110] and In re Indiana Federation of Dentists,[111] that condemned practices after brief rule of reason analyses. In In re Indiana Federation of Dentists, the Commissioners refused to apply the per se rule, then went on to assess the pro- and anticompetitive impact of the challenged behavior.[112] Because the Indiana Federation of Dentists'

(IFD) concerted refusal to furnish X-rays reduced consumer choice and impaired the insurance companies' ability to conduct cost containment programs, and because the IFD produced no evidence that the restraints were necessary for a legitimate pro-competitive purpose, the conduct was found to be an unfair method of competition in violation of FTCA 5.

In the Michigan State Medical Society (MSMS) case, the FTC refused to apply a per se rule analysis despite the close resemblance to price tamperings traditionally found to be unreasonable.[113] The Commissioners noted that, since the challenged behavior did not involve direct fee setting (as in Maricopa), they were not prepared to declare it illegal per se and close the door on all asserted pro-competitive justifications. In a truncated analysis of competitive effects, the Commissioners found that the MSMS's concerted attempts to pressure third party payers to accept changes in reimbursement policies involved a clear threat to competition, with only weak or non-existing offsetting benefits, and unreasonably restrained trade and violated FTCA 5. Commissioners Bailey and Pertschuk issued concurring statements arguing that a per se analysis ought to have been applied[114] a judgment that many antitrust courts may adopt in cases that they consider otherwise to be clear concerted refusal to deal cases.

In summary, courts are likely to continue to require evidence about the actual competitive effect of a challenged practice, and to permit defendants to rebut evidence of competitive effects by showing the positive value of the challenged practice. Given their unfamiliarity with the field and its peculiar market conditions, it is

likely that courts will carefully examine arrangements affecting the delivery and financing of highly technological medical services. The courts may remain open to arguments justifying restrictive or potentially anticompetitive health care delivery and financing arrangements, despite those arrangements' close resemblance to activities that would otherwise be characterized as per se offenses if they occurred in normal commercial settings. It is also likely that courts that are unwilling to apply per se rules to health care activities will look to jurisdictional and other defenses to avoid reaching the merits of the case at all. Those defenses having particular significance in health care cases are discussed in detail below.

G. DEFENSES TO ANTITRUST SUITS

1. THE LOCALITY DEFENSE

As noted above, the Sherman Act only applies to restraints or monopolization of "trade or commerce among the several states". A traditional defense to the application of antitrust laws to the learned professions was that their practices were often local and any effect upon interstate commerce was merely incidental and remote.[115] Recent Supreme Court decisions, indicate that this defense will not have broad application in health care cases.

Until 1975, federal courts had refused to find the requisite interstate commerce connection in many cases involving health care providers. The courts often sought a "direct" or "intended" effect of the alleged anticompetitive activity upon interstate commerce.[116]

However, the Supreme Court has moved away from this restrictive view of interstate commerce in antitrust cases in other industries[117] and, in 1976, the Court reviewed the "direct" or "intended" test in medical antitrust cases.[118] These cases[119] have expanded the meaning of interstate commerce to the point that nearly all commercial activities will be considered to have a substantial effect on interstate commerce. The United States Court of Appeals for the Tenth Circuit and several district courts, however, have recently made an effort to interpret these holdings more narrowly through the application of two tests.[120]

A defendant's anticompetitive behavior is subject to the Sherman and Federal Trade Commission Acts if it has occurred "within the flow of interstate commerce"[121] or if, on a local level, it has "substantially affected commerce".[122] The "affecting commerce" test is easier to establish, and allows federal antitrust laws to reach relatively far into local communities.[123]

In 1980 in McLain, a case involving an alleged, price-fixing conspiracy among local real estate brokers, the Supreme Court lowered further the interstate commerce barrier.[124] When the Supreme Court granted certiorari in McLain, there was confusion about which activity had to be in, or have a substantial effect on, interstate commerce. In Rex Hospital, the Supreme Court had looked at the plaintiffs' activities; but in McLain, it looked at the defendants' activities. The test thus seemed to be not the effect that the illegal restraint would have on interstate commerce, but the fact that the defendant's business had a substantial effect on interstate commerce.[125]

However, the Tenth Circuit Court of Appeals in Crane v. Intermountain Health Care, Inc,[126] has attempted to return to a pre-McLain approach. The majority of the Court stated that the language from McLain really meant that the defendants' challenged activities, and not their overall business activities, must have a substantial effect on interstate commerce, and held that the complaint failed to meet the interstate commerce requirement.

The Crane approach, has subsequently been rejected by the Court of Appeals for the third circuit in Cardiomedical Associates Ltd. v. Crozeer-Chester Medical Center.[127] and the Ninth Circuit has held that at the jurisdictional stage, a plaintiff need only make a showing that the allegedly unlawful restraint affects interstate commerce.[128]

While Crane and other cases adopting a similar interpretation of the Supreme Court pronouncements have somewhat muddied the water, the interstate commerce element appears easily satisfied under the McLain and Rex Hospital tests. Even if the Crane analysis were applied, the requisite effect on interstate commerce may be more easily found in the transplant area than in other areas of medical practice. While each situation must be analyzed separately, an effect on interstate commerce will probably be involved in organ retrieval and shipment, equipment purchase, organ recipient movement to out of state transplant facilities and many other components of transplant service delivery and financing.

2. THE "GOVERNMENTAL INVOLVEMENT" DEFENSE

Antitrust law generally applies only to anticompetitive behavior of private parties directed at other private parties. Health care actions that are taken in response to a governmentally imposed health planning scheme--actions that might otherwise violate antitrust laws--may be protected by one of three exemptions from the antitrust laws. Such activity might be protected under the "state action" doctrine where state law arguably mandates certain conduct by health care providers. Or, if a federal regulatory scheme conflicts with the application of the antitrust laws, the antitrust laws will be deemed to be repealed by implication. This "implied repeal" doctrine applies only to federal law and only to the minimum extent necessary to allow that federal regulatory scheme to operate. Finally, when competitors are seeking to influence governmental policy decisions, the first amendment rights of those persons, and the government's need to receive information have been considered too important to be threatened by antitrust prosecution. We shall illustrate the potential application of each of these defenses to transplant activity.

a. State Action Doctrine. In Parker v. Brown the Supreme Court held that certain conduct regulated by a state is not subject to the antitrust laws,[129] and has applied this ruling to recent cases. The most recent Supreme Court analysis is found in California Retail Liquor Dealers Association v. Midcal Aluminum, Inc.,[130] where the Court listed two preconditions to the application of the state action exemption: (1) the challenged restraint must be a clearly articulated and affirmatively expressed state policy, and (2) that policy must be

"actively supervised" by the state itself. Some commentators argue that the Court has recognized a third threshold criterion for state action: (3) that the conduct must be compelled by the state.[131]

The following cases illustrate the application of the Parker v. Brown conditions. Goldfarb[132] involved a challenge to a county bar association's promulgation of a schedule of minimum fees for certain legal services. The U.S. Supreme Court denied antitrust immunity, because the state court had not specifically required imposition of minimum fee schedules, and because a local bar association, although an official state body for some purposes, was nevertheless made up of private persons watching out for their own economic interests, and thus could not act with impunity.

Sherman Act immunity however, was, applied in Bates v. State Bar of Arizona,[133] which challenged a state Supreme Court rule prohibiting lawyers from advertising prices. While the state bar had a role in enforcing the ban, that role was completely outlined by the State Supreme Court, in contrast to the situation in Goldfarb. It had a clearly articulated state policy and actively supervised that policy in the course of its enforcement decisions.

Cantor[134] involved an alleged tying arrangement of light bulbs and electricity. No antitrust immunity was granted by the court, because "state approval seems to reflect state toleration of Detroit Edison's decisions rather than state compulsion of the utility."[135]

The state action defense will be crucial in the health care area in light of state health planning laws and their directives to

the local Health Service Agencies (HSAs) to encourage coordination and cooperation in delivery of costly forms of medical treatment. Critical questions will surround the "active supervision by the state" prong of the Midcal test. State health planning laws generally can go far in clearly articulating policies to limit competition in health care. However, a mere showing that a state has enacted a policy to eliminate competition is insufficient to establish state action. From Midcal, it appears that the state must actually review the anticompetitive conduct to ensure that actual state regulation, rather than mere authorization of private decisionmaking, is occurring.[136]

The supervision prong of the state action test could be extremely difficult to meet in health care. Although states may have policies advocating cooperation to achieve cost effective delivery of health care services, they may not actively supervise the activities of health care providers.

b. Implied Repeal Doctrine. A second exemption for allegedly anticompetitive activity rests on the doctrine of "implied repeal" of antitrust laws in direct and unreconcilable conflict with an activity necessary to carry out a federal regulatory scheme.[137] The court's first step is to determine if the particular anti-competitive activity, in the context of the regulatory scheme, can exist simultaneously with the antitrust laws. Application of the doctrine of implied repeal is not favored and thus will not be casually allowed; repeal will only be implied "where there is a 'plain repugnancy between the antitrust and regulatory provisions.'"[138]

The Supreme Court has repeatedly refused to find a blanket immunity for all activities that can be said to further the regulatory scheme and are not required, authorized, or subject to review by a government agency. The Court has favored implied repeal only when private conduct is specifically authorized by another federal statute and is subject to government review or, when the conduct is generally authorized, it is also consistent with the purposes of the federal regulation, and subject to pervasive federal regulatory authority.[139]

The implied repeal doctrine and its application to health planning was recently discussed in National Gerimedical Hospital and Gerontology Center v. Blue Cross of Kansas City.[140] Instead of applying the traditional narrow analysis used by the Supreme Court the trial court applied a blanket exemption for the defendant's actions taken pursuant to the National Health Planning and Resources Development Act (NHPRDA), and granted summary judgment for Blue Cross.[141] The Eighth Circuit affirmed the decision.[142]

The Supreme Court reversed, declining to find implied repeal for the planning activities in question. In so doing the Court stated that "(T)he action here was neither compelled nor approved by any governmental regulatory body. Instead, it was a spontaneous response to the finding of an advisory planning body, the local HSA."[143] National Gerimedical illustrates the Supreme Courts application of the implied repeal doctrine to the health planning area in the same way as to other areas of commerce. No blanket exemptions will be found for actions of health care providers that are taken in response to the health care planning process. However, the case leaves open the

possibility that some activities taken in response to planning recommendations by HSAs might be impliedly immune from antitrust scrutiny. The parameters of the implied repeal doctrine in health planning may become clear only after more litigation.

The parameters of the NHPRDA are themselves less than clear. Subsequent to the operative facts in Gerimedical, Congress amended the NHPRDA to add language regarding the role of competition in the allocation of health services. The amendments state that the strengthening of competitive forces in the health services industry is a national priority whenever competition and consumer choice can constructively serve to advance the purposes of quality assurance, cost effectiveness, and access.

Congress thus codified a recognition of the role of competition in health care. Unfortunately, its directive is vague at best; it seems to require that competition should be strengthened where it will advance the purposes of quality assurance, cost effectiveness, and access, and should be eliminated when to do so will advance those same purposes.

c. Noerr-Pennington Doctrine. The antitrust doctrine by which First Amendment rights are given priority over the antitrust laws is known as the Noerr-Pennington doctrine.[144] This doctrine protects concerted efforts to persuade a legislature or government agency to take a particular action with respect to a legislative or adjudicatory matter. However, the Supreme Court has recognized exceptions to the doctrine based on the type of activity and whether its purpose is genuinely to influence government action. Activity

that is a sham, "nothing more than an attempt to interfere directly with the business relationships of a competitor, is not protected.[145] In addition, the Noerr-Pennington doctrine would not immunize attempts to interfere with a competitor's access to governmental decisionmaking entities such as agencies, courts, or legislatures.

While various health care facilities may arguably be classified as "governmental agencies"[146] the Fifth Circuit Court of Appeals rejected a physician's Noerr-Pennington defense to a charge of participation in an illegal boycott.

d. Defenses Applied. The application of all three of these defenses can be illustrated by a hypothetical situation in which a Health Service Agency coordinates the delivery of services for heart transplantation and other highly technological treatments. Assume that an HSA took an active role in suggesting and implementing product market division described earlier in this paper, i.e., an agreement that one hospital in a metropolitan area would handle severe burn therapy, another, intensive neonatal care, and a third, heart transplantation.

An initial issue would be whether the enactment of the NHPRDA constituted an implied repeal of the antitrust laws so as to immunize the conduct of the HSA and the providers for this activity. While the language of the NHPRDA might be deemed authority to seek the cooperation of providers in coordinating service delivery,[147] Havighurst has argued that it does not amount to an implied repeal of the antitrust laws.[148] He argues that the statute is not sufficiently specific to warrant an exemption from antitrust liability

for any anticompetitive agreements that the HSA might work out between competitors.[149]

Both the Noerr-Pennington and the "state action" doctrines could be advanced to protect the HSA and providers working with it from antitrust liability. The HSA in our example could claim that it was a government instrumentality and therefore entitled to the state action exemption.[150] Providers acting with the HSA might claim an exemption from antitrust liability on the ground that they were merely petitioning a government body (i.e., the HSA), and, under Noerr-Pennington, competitors may confer over proposals to be submitted to the HSA for approval and incorporation in the agency's health plans.[151] If the HSA were viewed as a private rather than public agency, the HSA and the providers also could have claimed that they were acting jointly to advise the agency in a quasi-legislative function. Nevertheless, as Havighurst notes, all of these arguments would fail because of the probable lack of HSA power to bless anticompetitive agreements. Even if all activity leading to health plans and recommendations were protected, anticompetitive concerted action in implementing them still would be subject to antitrust scrutiny.

This type of problem prompted the 1979 amendments to the NHPRDA, but they did not explicitly (or implicitly) exempt all participants in medical facility consolidations, conversions, and closings as might be included in a state health plan.[152] Health planning laws thus probably do not immunize these types of agreements between competitors.[153]

A recent Department of Justice action bears directly on our hypothetical example, although it discusses obstetric services rather than heart transplantation. The Department of Justice dealt with an HSA request for an opinion on its plan to encourage hospitals offering obstetric services to "explore the feasibility of cooperative adjustments that will result in joint action to adjust the number of beds, physicians, and allied manpower, and division of services"[154] The Department singled it out as an example of activities that might be violations of the antitrust prohibition against agreements not to compete because it was not necessarily authorized or even contemplated by the NHPDRA. The Department also noted with approval that the HSA had stated in a revised request for an opinion that it would not engage in activities to implement plans involving concerted actions by providers. The Department of Justice presumably would apply the same analysis to a plan for division of heart transplantation.

H. CONCLUSION

In this primer, our aim has been to identify the potential application of antitrust principles to actions of participants in the transplantation service and financing "system." Our purpose has not been to analyze the economic characteristics of transplant activities, nor to assess whether it is possible or necessary to design regulations that would produce results superior to those of unfettered market interactions.

Our goal was to highlight potential conflicts rather than to voice opinions on the legality of any specific course of conduct. Our preliminary analysis indicates that there are several potential areas of conflict between the antitrust laws and current or foreseeable activities related to transplantation. Many of these areas should be analyzed more thoroughly.

Section 4 - SPECIAL MALPRACTICE ISSUES IN HEART TRANSPLANTATION

A. INTRODUCTION

In recent years, the frequency of organ transplantation has increased dramatically. Despite the surge in transplantation, transplant professionals have not experienced a corresponding increase in professional liability claims, in stark contrast to health care professionals working in other areas of specialty practice. However, the evolution of transplantation procedures into standard medical practice may portend more uncertain times for transplant centers and providers. As patient expectations rise, and increasing numbers of centers and professionals engage in transplant practice, increasing numbers of liability claims can be expected. Existing legal principles will provide some--but not all--answers for many of these potential liability issues.

The organ donation and retrieval process presents a number of interesting, and only partially resolved questions surrounding the responsibilities and potential liability of transplant centers and professionals. They include:

- How far does the Uniform Anatomical Gift Act's grant of "good faith" immunity for transplant professionals extend?
- May a physician be held criminally or civilly liable for his or her determination that death has occurred and organ retrieval may proceed?
- What effect do autopsy statutes have on organ retrieval efforts, and what is required of the transplant professional under these laws?

Referral and care of transplant recipients may also raise unique and highly complex legal issues. They include:

- Might health care providers in the future be held liable if they fail to refer persons with heart conditions amenable to treatment by transplantation to transplant programs?
- What role does--or should--informed consent play in transplant practice?
- What types of malpractice actions involving transplant providers can be anticipated?
- What liability exposure might the provider have for transplantation of a defective or diseased organ into a recipient?

This section outlines some of the current legal developments and as yet unlitigated questions that confront medical centers and professionals involved in retrieving and transplanting hearts.

B. LIABILITY FOR ACTIONS TAKEN WITH RESPECT TO THE DONOR

Court cases involving organ donation from living donors have generated much legal and ethical discussion. The courts have had to wrestle with the problem of defining when, and under what conditions, relatives may give legally valid consent for organ removal from mentally incompetent individuals or children in order to save the life of another family member.[1] Another litigated issue has been whether a donor may recover damages for organ removal by claiming that the donation was necessitated by negligent treatment of the donee.[2] These issues obviously do not come into play with cardiac transplantation since the only source of organs is the cadaveric donor. However, cadaveric organ retrieval raises some unique legal questions

of its own, questions that have garnered much less attention in both the courts and the literature. Three important issues that may affect providers involved in transplantable heart retrieval are: (1) the validity of consent for the use of the organs and compliance with the terms of the Uniform Anatomical Gift Act, (2) the timeliness of the determination of death, (3) the removal of organs when death is by violent means and the medical examiner or coroner has jurisdiction over the body.

1. CONSENT UNDER THE UNIFORM ANATOMICAL GIFT ACT

One of the first and most pressing issues in the early years of heart transplantation was whether removal of tissue from cadaveric donors could result in civil or criminal liability for those involved. At common law, a number of actions could be maintained for taking flesh from a deceased person. A cause of action could be based on allegations such as "mayhem," "mutilation of a corpse," or "unauthorized autopsy." The National Conference of Commissioners on Uniform State laws adopted the Uniform Anatomical Gift Act (UAGA) in 1968, in part to remove concern over potential legal liability for organ retrieval. Section 7(c) of the Act states:

> A person who acts in good faith in accord with the terms of this Act or with the anatomical gift laws of another state (or a foreign country) is not liable for damages in any civil action or subject to prosecution in any criminal proceeding for his act.

This "good faith" exemption is intended to protect the physician from legal action associated with the removal of organs from a dead person.[3] Moreover, there is disagreement over whether the

good faith exemption protects the physician against torts such as "wrongful death" or "premature declaration of death," or in cases where organ donation may itself cause death, as that term is traditionally defined.[4]

There is only one reported case in which a court has considered the tort liability of a physician or hospital in connection with the organ or tissue transplant procedures performed upon a donor who had been declared dead prior to removal of his or her organs or tissues. The court held that Section 79(c) of the UAGA immunized the physicians, insofar as they acted in good faith, from liability for conduct occurring after the donor's death, but did not apply to treatment received by the donor prior to death. In Williams v. Hoffman,[5] a treating physician informed the husband of a patient that his wife had died and obtained the husband's consent to remove her kidneys for transplantation. Over two days later, after a mortician reported that he could not locate the body, the husband learned that his wife's body had been kept functioning through life support techniques, and that she had not yet been pronounced officially dead. He attempted to contact the physician to stop removal of the kidneys only to discover that as he acted, his wife was declared dead and her kidneys were removed. He sued for assault and battery and negligence in his wife's name as the administrator of her estate, and for willful and intentional mutilation of a corpse, negligent mutilation of a corpse, and negligence in communicating an erroneous and premature death message in his personal capacity. The physicians asserted in defense that the husband had signed a valid consent form,

and that they had acted in good faith in reliance on the consent given by the plaintiff, and therefore they were immune from liability under the Act.

The Wisconsin Supreme Court held that the good faith exemption constituted an affirmative defense against the action brought by the husband in his individual capacity to recover damages against the physicians involved in the transplant operation, and the county in whose hospital the operation had occurred, for the mutilation of corpse charges and for negligence in communicating an erroneous and premature death message. However, the Court also held that the good faith defense did not apply to the actions brought by the husband in his capacity as administrator to recover damages for assault and battery and negligence. The Court pointed out that the UAGA concerned only the mechanics of giving and receiving anatomical gifts, the determination of the time of death, and procedures following death, but did not extend to treatment of the donor prior to death, nor to treatment of the live transplant donee. However, noting that the action brought by the husband in his own capacity did pertain to conduct covered by the terms of the Act, the Court held that the good faith exemption from liability did apply.

The husband also asserted that in actions arising out of transplant procedures, Section 7(c) unconstitutionally abrogated the rights of injured persons, in violation of the Wisconsin state constitution, by replacing the negligence standard of care with the lesser standard of good faith. The court rejected this argument by noting that since the UAGA did not affect liability for acts occurring

before the death of the donee, it did not affect the husband's right to sue for malpractice or assault and battery, and did not alter the standard of care for such causes of action.

The court also rejected the contention that the term "good faith" was unconstitutionally vague. It observed that the provision was not so uncertain as to make it impossible to execute or ascertain the legislative intent behind it with reasonable certainty. The court also rejected the contention that the section denied the husband equal protection of the laws in that it bestowed upon doctors, in the case of transplant operations, a special immunity not available in other malpractice cases. The court noted that the limitation on liability did not apply to treatment of the donor while still alive. Moreover, the court noted that any difference in treatment was justified by the legitimate public purpose of encouraging doctors to participate in organ retrieval, thereby increasing the supply of organs.

Finally, the court rejected the husband's argument that the good faith exemption violated a state constitutional provision (vesting legislative power in the state legislature by delegating power to determine state law) in that the section extended the limitation on liability to persons who acted in good faith in accordance with the anatomical gift laws of another state or foreign country.

Thus far, no cases have arisen alleging that physicians have acted in bad faith and thus are not immune under section 7(c). Generally, the "good faith" standard of care connotes a state of mind involving honesty of purpose, freedom from intent to defraud, and a

faithfulness to one's duty.[6] In a medical setting, this translates into good intentions, and honest exercise of the physician's best judgment about the needs of the patient. Bad faith, by contrast, is evidenced by actual or constructive fraud, intent to mislead or deceive another, or a neglect or refusal to fulfill some duty or contractual obligation not prompted by an honest mistake as to one's rights or duties, but instead prompted by some interested or similar motive.[7]

The question of whether a transplant provider has acted in "good faith" will always be one of fact, and will be determined on a case-by-case basis. However, the individuals involved in obtaining the consent of the family, and the physician who removes the organs should carefully observe the procedures for valid donation that are spelled out in the Act. If they do not, they will be open to charges of "bad faith" and may not be entitled to the immunity from liability which is detailed in the Act. Proceeding with organ removal with knowledge of a defect in the gift of the organ would almost certainly be unprotected.

One way that a physician might lose immunity would be to accept a donation from a relative of the deceased with knowledge that a relative of closer affinity to the donor or the donor him or herself objected to donation. The UAGA establishes a prioritized list of persons who may consent to donation of a deceased person's organs. It provides that a person in a class appearing on the list may donate only in "the absence of actual notice of contrary indications by the decedent or actual notice of opposition by a member of the same class

or a prior class" and that "..(i)f the donee has actual notice of contrary indications by the decedent or that a gift is opposed by a member of the same or a prior class, the donee shall not accept the gift." The physician who removes the organ will not always be the donee of the gift.[8] However, if a health care institution or provider involved in retrieving the organ has actual notice of a valid objection to the gift, notice exists of a procedural defect in the gift, and therefore the provider might lose immunity from suit.

Another way for the health care provider to lose immunity might be to knowingly act on a "stale" consent. A stale consent is one that is obtained from an appropriate family member a considerable length of time before the actual death of the donor. The Act stipulates that relatives or individuals other than the deceased may make the gift "after or immediately before death.[9] This section is susceptible to the interpretation that a gift made a substantial period of time before the death of the donor would be invalid. A physician who removed organs with actual knowledge that consent was not made in compliance with this requirement might not retain immunity from suit since he or she has knowledge of a procedural defect in the gift.

The most probable example of bad faith in this area would be to proceed with organ removal with knowledge that the gift of the organ had been validly revoked.[10] Failure to act in accordance with the terms of the Act would not in and of itself, establish criminal or civil liability. Rather, it would simply result in loss of immunity from civil or criminal action. Any civil action would undoubtedly

involve a substantial claim for emotional distress caused as a result of ignoring the wishes of the appropriate decisionmaker.[11]

2. DETERMINATION OF DEATH

Historically, one of the most difficult medicolegal problems in transplant practice has been determining the moment of the donor's death. The UAGA leaves the determination of the time of death to the attending or certifying physician, and makes no attempt to define the uncertain point in time when life terminates.[12] The issue of when a person is dead, so that organ removal can take place, is critical to the transplant process. As one commentator has noted: "To delay too long, so that metabolism ceases and tissue is damaged, can be fatal to the recipient. To act precipitately, when there is still a possibility of restoration of the donor is unthinkable."[13] If the donor is not legally dead at the time the declaration of death is made, the physician pronouncing death may also be open to charges of wrongful death or homicide. The potential for legal action has been exacerbated by the fact that "legal" and "clinical" definitions of death are not always the same. In Tucker v. Lower,[14] the brother of an organ donor brought suit against a transplant surgeon for $100,000, alleging in part that the donor's heart and kidneys had been removed before the donor was legally dead. He pointed to the fact that his brother's heart was still beating at the time death was declared as evidence that the donor was not legally dead. At the time, Virginia had not yet adopted a standard of death based on discontinuance of brain function. The trial judge initially refused to dismiss the case against the transplant surgeon, stating that death was to be

determined under the "cessation of bodily functions" standard developed by the common law. At the end of the trial, however, the judge instructed the jury that:

> In determining the time of death...under the facts and circumstances of this case, you may consider the following elements, none of which should necessarily be considered controlling, although you may feel, under the evidence, that one or more of these conditions are controlling: the time of the total stoppage of the circulation of the blood; the time of the total cessation of the other vital functions consequent there to, such as respiration and pulsation; the time of complete and irreversible loss of all function of the brain; and whether or not the aforesaid functions were spontaneous or were being maintained artificially or mechanically.

Although the jury found for the surgeon, the case nevertheless prompted the Virginia Medical Society to support a statute (later adopted) that recognized cessation of brain function as one ground for declaring death.[15]

Uncertainty over the appropriate definition of death is still creating problems for health care providers in some places. Another widely reported incident arose in 1980, but apparently did not result in legal action.[16] The parents of a 17-year old woman who had suffered severe head injuries consented to organ donation after a neurologist pronounced their daughter dead. While the daughter was being maintained on a respirator pending organ removal, a second neurologist examined her and pronounced that she was not legally dead. In the resulting confusion, the parents withdrew their consent for donation. The patient legally died sometime later.

A New York hospital also sought a declaratory judgment in a 1975 action to clear up uncertainties over application of neurological

brain death criteria. In New York City Health and Hospital Corp. v. Sulsona,[17] the hospital asked a court to construe the meaning of the time of death provisions in the New York Anatomical Gift Act in light of the fact that New York had no statutory standard for determination of death.[18] The anatomical gift act section provided only that "[t]he time of death shall be determined by a physician who attends the donor at his death, or, if none, the physician who certifies death." Despite the fact that the comments to the Uniform Anatomical Gift Act state that it is not intended to define when death occurs, the trial judge held that "[t]he context in which the term "death" is used in [the Act]...implies a definition consistent with the generally accepted medical practice of doctors primarily concerned with effectuating the purposes of this statute."[19]

The legal and medical uncertainties produced by the gap between the varied legal definitions of death and the advances in modern medicine has resulted in some legal movement toward adoption of "brain death" as the legal standard of death. Legislators in more than half of the states have enacted laws that permit reliance on brain related criteria for determining death.[20]

In addition, courts in several states have judicially recognized brain death standards in the absence of statutory recognition.[21] However, the standards adopted in the various states are not uniform. At least six varying standards exist; and many have been criticized as unworkable or outmoded.[22]

Moreover, mere recognition of brain death criteria does not end liability concerns for physicians who make the determination that

death has occurred. Physicians may have some legal exposure if they use brain death criteria more liberal than those contained in the relevant statute, or if they simply make an error in assessing whether legal death has occurred. While the Uniform Anatomical Gift Act clearly protects the surgeon who in good faith removes an organ, relying upon another's declaration of death, it is not at all clear that immunity extends to the physician who makes the actual determination of death.

Several writers have suggested that the "good faith" immunity provision in section 7(c) of the UAGA would not bar legal claims against a physician making the determination of death. First, they argue that a court or a jury is unlikely to find that a physician or surgeon who acted negligently by making a premature declaration could meet the "good faith" standard required for immunity under Section 7(c). Second, a premature declaration of death would not be "in accord with the terms of [the UAGA]" since the Act specifies that is is not intended to override other statutorily or judicially enacted standards for determining death. Third, many argue that the statute was intended to immunize physicians and surgeons from civil and criminal liability only for actions taken after the donor is dead.[23]

By contrast, other writers argue that the good faith defense would apply to physicians who make the determination of death.[24] Jeddeloh and Chatterjee state that:[25]

> To suggest . . . that the treating physician's decision as to time of death, critical in the transplant procedure, is not covered is to ignore important protections of the Act. While it is true that gifts under the Act do not take effect until after death, the

> Act discusses considerably more than just the mechanics of a gift. Section 7(b) directs that the time of death is to be determined by the treating physician, and therefore, when he determines death, he is acting pursuant to the Act. Since section 7(c) protects anyone who acts pursuant to the Act from both civil and criminal liability, the treating physician is so protected when he determines the time of death.

No cases have yet dealt directly with this issue. However, one court has implied that the 7(c) exemption for physicians acting in good faith in accordance with the terms of the Act applies to physicians making a determination of death.[26]

The question of whether the good faith defense will apply to determinations of death, and the extent to which it may shield physicians from suit for premature declaration of death is as yet unclear, and will remain so until case law around this section of the UAGA develops.

3. MEDICAL EXAMINER AND CORONER CASES

A large number of heart (and other organ) donors are victims of traumatic injuries, usually to the head. These injuries often occur under violent or suspicious circumstances in which a police investigation or autopsy may be considered. Under normal procedures, the time delay inherent in these processes rule out use of the victim's organs for transplantation because of rapid tissue deterioration. However, organ removal prior to investigation by the medical examiner or coroner's office may lead to questions over whether evidence relating to the causes or circumstances of the death has been destroyed.

Under the Uniform Anatomical Gift Act, organ retrieval has a lower priority than the requirements of autopsy and investigation by the medical examiner or coroner; Section 7(d) specifies that the Act is subject to all laws regarding autopsies. In many cases, however, the medical examiner or coroner and the transplant team can work together to coordinate organ removal and investigation and/or autopsy.[27] The Dade County, Florida, Medical Examiner has established a formal program of cooperation with transplant programs[28] The transplant team, attending physician or the hospital immediately notifies the Medical Examiner of potential deaths that fall under the jurisdiction of the Medical Examiner's Office, and provides the Medical Examiner's Office with the history, the circumstances of death and other pertinent information. The Medical Examiner's Office then decides whether it will permit organ retrieval (with, of course, legal consent by the donor or next of kin and after a determination of death has been made.) The Medical Examiner is generally present at the time the organs are removed. If the Medical Examiner is not present, then the removing surgeon must detail in writing the surgical procedures used and the absence of injury to the affected area of the body. In order to show that the declaration of death and subsequent organ removal were not independent, intervening causes of death, the following facts are documented in writing: (1) the circumstances surrounding the injury; (2) the status of the victim when first viewed at the scene or examined at the hospital; (3) the status of the victim at the hospital; (4) documentation of the evidence leading to the declaration of death; (5) documentation of

absence of injury or other potential causes of death related to the donated organs; and (6) documentation of the medical examiner's or coroners autopsy findings.

In Texas, cooperation is mandated by state law. A Texas statute requires transplant centers to notify the Medical Examiner's Office of a death falling within their jurisdiction. The Medical Examiner's Office then sends a representative to the transplant facility to perform an inquest, and if necessary an autopsy. If an autopsy is required, the organ needed for transplantation is first examined for clinical evidence and then released for transplantation.[29]

Cooperation with the Medical Examiner's or Coroner's Office and the local prosecutor (in suspected criminal cases) may also avoid legal difficulties. It is particularly important in cases of potential criminal prosecution to obtain the permission of the prosecuting attorney with jurisdiction over the case, in addition to the consent of the Medical Examiner or Coroner. While the permission of the prosecutor is not legally required in most states,[30] it avoids potential charges of interference with criminal law enforcement through destruction of evidence. Prosecuting attorneys generally will grant permission when they are assured that donation will not compromise the testimony regarding the cause of death.

C. LIABILITY ISSUES AFFECTING POTENTIAL AND ACTUAL TRANSPLANT RECIPIENTS

Transplantation practice involves legal ramifications not only because it involves interventions upon a donor, but because it may

affect potential and actual transplant recipients as well. As will be discussed below, medical malpractice and informed consent issues involving organ recipients will undoubtedly be raised as transplant-tion is increasingly utilized. However, this section starts with a discussion of another, rather unique question. Can a health care provider be held liable for negligently failing to: (1) advise a patient who may be a good transplant candidate of the existence of transplantation as a viable form of therapy, and (2) refer the patient for such an evaluation?

The answer is "perhaps." As a general rule, physicians have a duty to advise their patients of alternative methods of treatment for their illness. Failure to explain a standard treatment alternative, if one exists, is generally held to be negligence.[31] Courts have held that the duty to inform the patient of treatment alternatives exists even though the physician may not be competent to offer all those forms of treatment him or herself. The physician thus retains a duty to acquaint the patient with general information about treatment alternatives and to refer the patient to another health professional who performs the treatment.[32]

In most typical cases involving the failure of the physician to inform, liability is rooted in the failure of a physician to keep up with advances in the medical profession.[33] One likely reason that physicians may fail to recommend heart transplantation to their patients who are nearing the final stages of cardiac disease is that they are simply unaware of the advances in transplant practice. However, heart transplant cases differ from the usual situation in two

respects. First, despite increasing survival rates, heart transplantation undoubtedly is still considered outside the realm of standard practice by many. Second, unlike many forms of treatment, resource scarcity may play a role in determining liability for failure to inform. Because of the limited availability of donor organs, there is simply no guarantee that a person who is medically suitable for transplantation will be able to undergo treatment. These two factors may influence courts on the question of whether a duty to inform exists at all. Failure to prove that treatment could have been obtained, even if the physician had advised the patient of it, will also be a factor in determining whether the failure to refer "caused" the injury to the patient. Because of the perception that the likelihood of acceptance is small, even the physician who accepts the therapeutic value of transplantation may not wish to advise a potential transplant candidate of the possibility of transplantation.[34]

An initial question in any "failure to inform" case will be whether heart transplantation is an option that must be disclosed to an individual who may be a good transplant candidate.[35] An important question is, complicating factors aside, at what point a procedure becomes sufficiently standard or accepted that the physician has a legal duty to advises his or her patient of its existence and perhaps make a referral? This question again raises the thorny issue of the impossibility of pinpointing any meaningful dividing line between experimental and therapeutic medical care. While a physician may not be convinced of the efficacy of the treatment, as long as

reasonable medical opinion would consider it acceptable, he or she probably should inform the patient of the alternative. As one writer has stated:

> which risks the patient chooses to run are, in most cases, value judgments which fall entirely outside of the scope of medical decisionmaking and involve social, economic, religious and personal considerations that the physician cannot possibly know.[36]

The level of knowledge expected of physicians about transplantation may differ depending on their location and type of practice. Most health care providers today are aware of heart transplantation, but some may not be acquainted with the advances in and increasing usage of the procedure. The law in many jurisdictions may recognize that it is not realistic or fair to expect all physicians to exhibit the same level of sophistication and awareness of advances in cardiology. Some courts have held that the duty of a general practitioner to inform is limited to that which a reasonable general practitioner should know. Likewise, the duty of the specialist to inform is limited to matters which a reasonably knowledgeable specialist in this field would know.[37] For this reason, it is far more likely that a claim of failure to inform could be made against a cardiologist or cardiac surgeon than against a small town general practitioner. However, as transplantation becomes more widely practiced and successful, perhaps even non-specialists may incur a duty to inform cardiac disease victims of the option of seeking a transplant.

Breach of a duty to inform cannot, however, be equated with legal liability. Even if the physician's failure to inform a patient of the possibility of transplantation is a breach of a duty to the patient, the patient still has to prove that the failure caused him or her some injury and damages. At this point, facts concerning the probability that the patient would have been accepted into a transplant program in time to ward off death,[38] and the likelihood of a successful outcome would become extremely important.

1. INFORMED CONSENT OF THE TRANSPLANT RECIPIENT

Since the beginning of the century, courts have recognized that a physician must obtain a patient's consent to treatment. Justice Cardozo, in the famous 1914 case of Schloendorff v. Society of N.Y. Hospital,[39] stated that:

> Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages.[40]

During the first half of the century, the physician's potential liability was based exclusively on the tort of battery To avoid liability, the physician merely had to obtain the patient's consent to be treated; courts were not seriously concerned with the question of whether the patient truly understood the nature and effects of the proposed treatment.[41] However, the last quarter century has seen a dramatic increase in public consciousness concerning the patient's right to be actively involved in treatment decisions. Starting with a 1957 decision,[42] courts began to combine the physician's duty to

secure consent with a new affirmative duty to get an "informed consent;" that is, to disclose information prior to obtaining consent about the proposed treatment and its effects. Under this new theory, the focus of the physician's liability began to shift from battery to negligence. Currently, in most states, failure to obtain an informed consent is a type of professional malpractice subject to the standards of negligence law.[43] The courts generally hold that the physician has a duty to disclose to the patient:

- the patient's condition or problem;
- the nature and purpose of the proposed treatment;
- the risks and consequences of the proposed treatment;
- any feasible alternatives to the treatment; and
- the patient's prognosis if the proposed treatment is not given.

While health care providers now are undoubtedly more sensitive to the need to make the patient an active participant in the decisionmaking process, physicians have often tended to "cut corners" in obtaining consent to treatment, especially when the treatment is a serious intervention and retains an element of unknown risk. There is a temptation to bolster the often critically ill patient's confidence. In addition, physicians and researchers may fail to fully inform their patients of material facts because faith in the potential benefits of a new medical procedure subtly erodes the willingness to regard the patient as a full partner in the undertaking. One commentator has noted that:

> This is especially true as medical procedures become increasingly complicated and a corps of specialists, rather than a lone physician, treats a patient for a catastrophic disease. The physician, often a surgeon, who is in charge of this veritable army, understandably has the upper hand in the doctor-patient relationship. Indeed, he may be the originator of a new technique which offers a desperate patient a "chance for a cure" which he cannot get from any other practitioner... having the patient place himself entirely within the physicians hands has been an accepted part of medical ideology, justified by the physicians concern for the patient's well being and his alleged need for complete freedom to undertake whatever steps are believed necessary to promote it. But the risk is great, especially in experimental medicine, that the patient's abdication of his decisional authority will convert him from an end in himself to a means that is employed along with others at the physicians command to serve the goal of the procedure, as defended by the physician and his peers.[46]

When Christian Barnard performed the first human heart transplant for Louis Washkansky, he considerably overstated the probability of success, leading Mr. Washkansky to believe that heart transplantation had an 80% chance of success, even though that figure only applied to the chance of living through the operation itself. Dr. Barnard's justification was that:

> He had not asked for odds or any details...he was at the end of the line...for a dying man it was not a difficult decision...if a lion chases you to the bank of a river filled with crocodiles, you will leap into the water convinced you have a chance to swim to the other side, but you never would accept such odds if there were no lion.[47]

This account of the first "consent" to heart transplantation dramatically illustrates the temptations and rationalizations that underlie the tendency to avoid fully informing the patient of the likelihood of successful treatment. From a purely clinical

standpoint, the physician may feel strongly that the proposed intervention is the "best decision." However, it is the patient's legal and, most would venture, moral right to be afforded an opportunity to make his or her own "best" decision based upon his or her own personal values, knowledge and beliefs. The legal principle of informed consent is designed to prevent the physician from placing his or her thumb on the scale by misrepresenting or failing to present important information. The physician is in no position to weigh all of the intensely personal factors that may be of extreme importance to the patient: Will the pain be worth the procedure when chance of survival is uncertain? Will a slower, probably more peaceful death be preferable to undergoing the trauma of major surgery and a large possibility of later death by rejection or infection? Will the financial and emotional burdens on the patient and the family be justifiable in light of the risks?

What, then, should the transplant provider disclose to the recipient in order to obtain an informed consent? The two most critical elements of informed consent to transplantation are ensuring that the patient fully understands (1) the material risks and possible complications associated with transplantation, and (2) the likelihood that the transplant will succeed. Beyond current legal requirements, a truly "informed consent" to heart transplantation may also involve acquainting the patient with the often serious fiscal and psychological ramifications that transplantation can have for the patient and his or her family.

a. The Diagnoses. The duty to obtain an informed consent from the patient includes the duty to tell the patient what his or her condition or problem is. Failure to disclose the diagnosis is rarely the basis for a lawsuit, however, since diagnosis is commonly discussed in the physician-patient dialogue. In the normal situation, the patient should be informed of any significant reservations that exist over the diagnosis. Problems in this area are not significant in heart transplant cases, since diagnosis of cardiac disease occurs before the transplantation is considered and virtually all potential recipients would be aware of their diagnosis and its accuracy.

b. Nature and Purpose of Treatment. The nature and purpose of the proposed treatment must be explained to the patient in non-technical terms. In the case of transplantation, the explanation should include not only the nature of the transplant itself, but also the pre- and post-operative treatment regimens, including the necessary drug regimens, physical therapy, and continued care requirements.

While this part of the informed consent process is important to convey to the patient to foster truly informed and voluntary consent, it has seldom been a topic of litigation.[48] This probably stems from the fact that the diagnosis is an item about which the patient is generally curious and the provider is likely to volunteer information.[49]

c. Feasible Treatment Alternatives. An essential element of the patient's decision to undergo a proposed treatment is knowledge of the available alternatives. Several courts have held that consent

is not informed unless the health care provider discloses to the patient at least those alternatives that would be generally acknowledged within the medical community as feasible in the patient's case.[50] As discussed earlier, the physician may have a duty to inform persons for whom heart transplantation would be feasible that it is a viable treatment for them. However, the physician also has a duty to inform potential transplant candidates of other treatment regimens, even though there are few, if any, alternative treatments for persons with end-stage cardiac disease.

d. Prognosis if Proposed Treatment is Not Given. The final, traditional element of informed consent is a projection of what will happen without the proposed treatment. Cases involving this element are rare, probably because physicians typically utilize this information to guide patients toward a recommended treatment alternative. A dispute involving this item is also unlikely in transplant practice since nearly every potential recipient is aware that prognosis for long term survival is poor in the absence of a transplant.

e. Material Hazards and Possible Complications of Treatment. Most of the litigation surrounding informed consent has centered on allegations of failure to inform the patient of material hazards and possible complications associated with treatment. The most well known discussion of this element of informed consent occurred in a landmark case, Canterbury v. Spence.[51] In Canterbury, a surgeon failed to tell his 19-year old patient that the proposed treatment, a lumbar laminectomy, carried with it about a one percent

risk of paralysis. The patient agreed to the operation, but later suffered paralysis. He sued, claiming in part that he would not have agreed to the operation had he known of the risk that he might be left paralyzed. His physician defended the decision not to inform the patient of the risk by stating:

> I think that I would not tell patients that they might be paralyzed because of the small percentage, one percent, that exists. There would be a tremendous percentage of people that would not have surgery and would not therefore be benefitted by it, the tremendous percentage that get along very well, 99 percent.[52]

However, Canterbury set forth the principle that the physician cannot keep important pieces of information from a patient solely out of the belief that he or she can best weigh the risks of treatment against its beneficial effects. The district court's verdict for the neurosurgeon was therefore reversed.

Not all risks, no matter how slight or remote, need to be revealed to the patient. The doctrine of informed consent holds that only material risks need be revealed. In states that use an "average patient standard," the definition of material risk is often the one first articulated in the Canterbury case:[53]

> A risk is material when a reasonable person, in what a physician knows or should know is in the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy.

The courts have not attempted to define a specific probability that triggers the disclosure requirement. Generally, the necessity of disclosure is determined by weighing both the probability that the

risk will occur and its potential severity. Thus, a physician may not be required to disclose that a 5-10 percent risk of greater complications could lengthen the patient's recuperation. However, one court has held that any risk of death, however slight, must be disclosed.[54] This standard obviously creates uncertainty for the health care provider, since he or she must often "guess" what the average person would want to know.[55]

There are many risks to heart transplantation that would be considered "material." Heart transplantation is attendant with hazards and consequences, both known and unknown. Some of the several known risks of heart transplantation that would likely be considered material include those discussed in the material below.

1) Infection. Successful heart transplantation always involves the use of immunosuppressive drugs that chemically suppress the normal bodily defense responses against pathogenic microorganism and foreign tissues.[56] However, one of the serious effects of immunosuppressive drugs is that they seriously handicap the transplant recipient's ability to ward off infection. Infection is therefore one of the most frequent and serious complications of transplantation. As a risk with serious--and perhaps fatal--complications, the possibility and likelihood of post-transplant infection is a risk that should be disclosed to the patient.

2) Graft Rejection. Successful organ transplantation is also limited by immunologic rejection of the transplanted organ by the recipient. Immunosuppressive agents can prevent or delay rejection episodes in many, but not all, individuals. The incidence of

mortality in cases of rejection is quite high, and the incidence of increased side effects from augmented dosages of immunosuppressive drugs is also increased. The possibility of graft rejection and the possible known side effects that may result from augmented doses of immunosuppressive drugs are also risks that should be made known to the patient.

3) The Risk of Transplant-Related Cancer. Immunosuppressive agents can also cause a wide variety of malignant diseases in transplant recipients. The reported incidence of cancer in all types of transplant patients surviving more than four years after transplant approaches 25 percent.[57] Cancer can also be transplanted from the donor to the recipient. Although many transplanted cancer cells would be rapidly destroyed if implanted in a healthy individual, cancer cells implanted into an individual via allograft may thrive due to the immunosuppressed state of the recipient. Cancer transfer also carries some risk of malpractice claims as well, since it might be alleged that proper precautions were not taken in examining the donor and the available medical history for signs of malignancy.[58] However, due to the short amount of time that the heart is viable, failure to ascertain the presence of cancer that it not externally apparent on the organ or apparent from the donor's treatment or available records would probably not be considered malpractice.

4) Miscellaneous Complications of Transplantation. In general, the recipient ought to be made aware of possible material risks and consequences involved with transplant surgery and any

exacerbations of the usual risks of surgery associated with transplantation. Many other risks are involved in transplantation, and most are either caused or exacerbated by the use of immunosuppressive agents. Aside from types of cancer, transplanted organs may, with potentially serious results, also carry undetected diseases or infections into the immunosuppressed patient. Other, more rare (but serious) complications include hypersplenism,[59] an excessive destruction of one or more types of blood cells in the spleen,[60] death of bone tissue in the adult, or death of a vascular tissue and failure to grow in children,[61] and interstitial pneumonia.[62]

Heart transplant practice and treatment regimens are advancing and will continue to evolve, and transplant specialists are continually learning more about the long- and short-term risks and complications of transplantation. One of the more difficult questions concerning what should be disclosed to the recipient is: "How can one make known to the patient the risks of new and evolving techniques when not all is known about new aspects of treatment and their potential side effects?" The informed consent literature indicates that the transplant provider should, at a minimum, candidly relate to the potential recipient that heart transplantation involves as yet unknown or little understood risks and complications beyond those already divulged. The physician has the added duty of discovering as much as possible about new techniques and drug regimens that he or she proposes to use. At a minimum, this would include making a thorough

inventory of the risks of such techniques and regimens that have been described in the literature.[63]

5) Probability of Success. Another crucial element of a fully informed consent is an accurate assessment of the likelihood that the heart transplantation will be successful, both in terms of survival and degree of rehabilitation. An unresolved issue that the transplant provider must determine is which survival data to use--those of all transplant centers or those of the transplant center at which the recipient will undergo treatment.[64] Whatever data are used, the tenets of informed consent would dictate that the temptation to skew the odds be carefully avoided.[65]

Courts generally have focused on medical factors when forming the requisites for informed consent. However, heart transplantation and other types of catastrophic disease treatment decisions may be more profoundly affected by social and psychological factors than by strictly physiological considerations. Courts conceivably may expand the list of legally "material" items that must be disclosed to the patient to include:

- the impact of the proposed procedure on the patient's family or job situation;
- the likely cost of the proposed treatment and any necessary drug regimens and followup visits;
- the necessity and cost of assuming residence close to a treatment center for an extended period of time; or
- the probability that the procedure and followup treatment would be covered by the patient's insurance.[66]

There may be sound arguments for not expanding the health care provider's advisory capacity to include matters that are not strictly medical. However, especially in catastrophic disease treatment, many of these non-medical considerations are of utmost concern to the patient and may tip the balance in deciding whether or not to accept treatment. This is particularly true with procedures such as heart transplantation, because a successful outcome cannot be assured and the potential risks are high. Courts may feel that it is the provider's duty to disclose, or at least disclaim consideration of, the social and economic effects of treatment and non-treatment of which the provider is aware.

f. The Requirement of Materiality and Proximate Cause In cases asserting a lack of informed consent, as in medical malpractice, liability exists upon proof that a duty was breached, and that the breach caused injury to the patient. When the breach of duty lies in not disclosing, or in misrepresenting, pertinent information to a patient, there is no liability unless the plaintiff would have chosen a different course and thereby avoided the injury had the information in question been disclosed. This causal "link" between nondisclosure or misrepresentation and the resulting damage or injury is what is meant by the term causation or proximate cause.

"Causation" in the informed consent context means that the patient cannot recover without a showing that he or she would have made a different treatment decision had the information at issue been disclosed. Proving this element can be a substantial obstacle in many types of cases. As one writer has noted:

> The patient's ability to convince a court of the existence of proximate cause turns on several factors. Key among these are the severity of the patient's condition, which bears on how likely it is that the patient, as a reasonable person, would have challenged the physician's judgment, and the availability of treatment alternatives. Generally speaking, a patient who had no sensible choice but to accept the proposed treatment will not be able to prove causation.[67]

For virtually all transplant candidates, the alternative to transplantation is acceptance of palliative care and death within a short period of time. In order to prevail in a case alleging lack of informed consent to transplantation, the patient (or next-of-kin) must show that, had all information material to the decision been disclosed, a reasonable person would have chosen palliative care over heart transplantation. Many courts and juries may be unwilling to say that the reasonable patient under any circumstances would choose death over life after a transplant, however, short and painful that life may turn out to be.[68] However, in the current era, when "death with dignity" has become an increasingly visible concept, successful suits are not out of the realm of reality. For instance, where the patient was not informed of the possibility of serious post-transplant malignancy, a court or jury might be willing to find that a reasonable person would choose death from end-stage cardiac disease over a prolonged, cancer-related death complicated by the other effects of transplantation. (Of course, the next difficulty would be assessing damages.) In addition, if courts grow more sensitive to the non-medical implications of transplantation, they may also be willing to consider non-medical harms as well. For instance, a jury may accept the notion that a patient may not have accepted the financial

and emotional hardships of transplantation had he or she been fully aware that in his or her particular case, the probability of prolonged, healthy survival was only 40 percent.

While the potential for civil liability is small, the legal (and most would maintain ethical) duty to disclose remain unchanged. Moreover, as Katz and Capron note, informed consent to catastrophic disease therapy serves many purposes beyond protecting the provider from liability. Its purposes include:

(a) promoting individual autonomy;

(b) protecting the patient/subject's status as a human being;

(c) avoiding fraud or duress;

(d) encouraging self scrutiny by the physician-investigator;

(e) encouraging rational decisionmaking; and

(f) involving the public.[69]

Despite the low probability of civil liability, these other values and purposes still suggest that emphasis must be placed on obtaining informed consent from heart transplant recipients.[70]

D. LIABILITY ISSUES IN CARING FOR THE RECIPIENT

If hospital risk managers and attorneys in institutions with transplant programs were asked, most would agree that potential and actual organ recipients are not likely to bring malpractice suits against their transplant centers or the health care providers involved in their care. Some of the reasons are probably related to social factors; providers and recipients and their families may develop a

close relationship that contrasts markedly with the impersonal nature of other areas of highly technological medical practice.[71] Moreover, most of the surgeons and the centers involved in transplantation at this time have solid reputations for skill and expertise. Finally, patients and their families probably tend to view a transplant with lowered expectations of success, and therefore, are prepared for less than satisfactory results. Some of the reasons may also be traceable to the difficulties in proving a case of malpractice and getting any sizable recovery in court; in areas of medical practice that have not yet completely evolved a set of standard procedures, and are occupied by a relatively small number of providers, it may be extremely difficult to define a standard of good practice against which to measure the care provided and the techniques used by the transplant team. It may also be extraordinarily difficult to obtain needed expert testimony.[72] Even if a standard can be developed, it will nevertheless often be extremely difficult to establish a causal connection between any failure to act according to professional norms and the resulting injury or death. While success rates are climbing steadily, even under the best conditions, many transplant recipients still die or experience serious complications or side effects.[73] It may be extremely difficult to distinguish unavoidable harm from that traceable to provider "fault." The issue of damages to the recipient may be extremely difficult to win in front of a jury. Since the recipient surely would have died without the transplant, or might have died under the best of conditions, juries may not be easily persuaded that a recipient suffered any loss if he

or she dies or suffers complications as a result of poor practice. Damage elements such as lost earning capacity, and reduction in life expectancy may be extremely difficult to resolve since both are affected by the transplant procedure itself.

The issues do merit discussion, however, since the likelihood of a law suit increases as the procedure becomes more widely utilized, and may be easier to win as reported cases begin to appear. Indeed, one case involving charges of medical malpractice and lack of informed consent involving heart transplantation has already been reported.[74]

Transplantation practice will give rise to both standard and more unusual liability claims. Standard malpractice cases may involve claims that transplantation was contraindicated,[75] that the transplant failed due to faulty surgical technique, that known side effects were not recognized and treated, that anesthesia was not properly administered, or that the transplant center did not exercise due care in its choice of transplant professionals.[76]

Heart transplantation may also involve a more unusual set of liability issues because it involves introducing another's tissue into the recipient, and because the individual is immunosuppressed. Transplantation requires that donor organs be correctly removed from the donor, free from injury, and uncontaminated by bacteria that can lead to fatal infection, or graft failure. The organ must also be maintained in a viable state until transplanted. Moreover, the organs must be surgically removed so as to leave enough tissue to assure good connections with the recipient's arteries and veins.[77]

Even in patients who are not immunosuppressed, the introduction of diseased or defective tissue can have disastrous consequences. Transfusion of diseased or mismatched blood, for example, can have serious, or even fatal consequences, as illustrated in a number of ensuing court cases.[78] Immunosuppression multiplies both the number and intensity of possible adverse reactions to introduction of disease via the donor's tissue. As stated earlier:

> it has been abundantly confirmed that malignant cells transferred with an allograft can thrive in the unfortunate immunosuppressed patient, in marked constrast to normal individuals where transplanted cancer cells are rapidly destroyed.[79]

Serious infections can also be transplanted, and again are far more serious for immunosuppressed individuals. The organ itself may be damaged or malformed due to coronary artery disease, or previous heart attacks.

An issue that will surely be raised, if not litigated, in the future concerns the duty of the transplant health care provider to detect diseases or defects that may result on injury to the recipient. Generally, two types of charges can be expected when tissue introduced into another is suspected to be diseased or defective. The first is ordinary negligence or "medical malpractice." The second is strict liability without fault.

1. MEDICAL MALPRACTICE OR ORDINARY NEGLIGENCE

In most medical malpractice cases, a patient alleges that he or she was injured because a health care provider failed to follow the standard of care expected of a reasonably prudent health care

professional under the circumstances. Normally, proof of existence of a standard course of treatment and deviation from that course, along with evidence that the deviation caused the resulting injury, and proof of damages constitutes malpractice. However, in most instances, a health care provider who follows accepted procedure for diagnosis and treatment will not be held liable, even if the outcome of the procedure is poor.[80] Malpractice then, will not come into play unless the bad result was caused by a failure to conform to an appropriate standard of care.

The blood transfusion cases indicate, as a beginning point, that the provider will not be held liable under negligence theory for diseases and defects in the organ that are not discoverable in the exercise of due care.[81] The challenge will come in defining what "due care" will be. In the case of blood transfusion, providers have been held liable for injuries sustained through transfusion of blood tainted with syphillis, since adequate tests are available to detect its presence.[82] However, liability under negligence theory has not been applied to cases involving transfusion of serum hepatitis since reliable tests to detect it have not been developed.[83]

In the case of transplantation, liability will also not attach under negligence theory unless the defect or disease was discoverable in the exercise of due care. By way of example, the presence of cancer cells in the donor organ may not, in many instances, be discoverable since they may not be detectable through an examination of the donor, feasible tests, or the available medical history of the donor, especially given limitations on the viability of

the organ outside of the donor's body. In addition, a potentially serious stumbling block will be establishing the applicable standard of care. Courts are likely to focus on questions such as: what tests, investigation, and procedures must be used to conform to the standard of care exercised by providers in the relevant community?[84] In most instances, courts look to the practices of other providers in the same field. The transplant literature indicates that a medical history should be taken to rule out presence of most forms of carcinomas in the donor,[85] as well as other conditions like presence of sepsis or infection.[86]

As yet, an unresolved issue is how exhaustive the investigation into possible diseases or defects should be. Litigants will be concerned about issues such as the types of information that is (or should be) obtained from the donors family; whether the family, as the most convenient source of information about the donor, is routinely asked, in specific or general terms, about possible presence of diseases or defects that may affect suitability as a transplant donor? Courts conceivably may place a duty on the provider to investigate the medical history of the donor. Obviously, transplant providers will be concerned about discouraging donation by asking distraught family members detailed questions. Courts faced with this issue will have to look to expert testimony, and perhaps other sources to discern just how thorough one should be. They will also undoubtedly be concerned with the practices concerning examination of any available medical records. Attention may also focus on the sufficiency of testing for presence of disease in the donor, since the

literature indicates that potential donors indicating signs of sepsis should be rejected.[87] In addition, age of the donor is also important. And, since poor graft function is correlated with advanced donor age, Copeland and Stinson suggest that donor males over 35 and females over 40 with negative cardiac histories should be subjected to coronary arteriography and cardiac catheterization to determine viability of the organ prior to transplantation.[88] Courts may incorporate this type of testing into a standard of care as well. Courts may also look to whether an appropriate visual examination of the organ was undertaken to detect defects and disease.

Analogies to cases involving other types of medical procedures are difficult to draw since the condition of donor tissue is rarely a factor in malpractice litigation outside of the blood transfusion arena. However, one case has been reported involving an allegation of negligent selection of a cornea donor. In Ravenis v. Detroit General Hospital,[89] a court found a hospital liable for the failure of its staff members to take appropriate precautions in selecting and testing a cornea donor. The case involved two patients who received corneas from the same donor, and who both lost sight in one eye due to infection. At the time of the transplantation, published criteria existed, that were fairly standard throughout the medical community, for the acceptability of cadavers as eye donors. Those standards contraindicated the use of corneas from donors with a history of: (1) long term debilitating disease, (2) systemic disease, (3) acute infection, and (4) demonstrable infection within the blood stream.

A physician also testified at trial that examination of the cornea under a slit lamp bimicroscope was required to determine the acceptability of the eye for cornea transplant, and that although the hospital had such equipment it did not routinely perform an examination. The doctor who removed the corneas testified that he did review the donor's medical records and found no evidence of contra-indications. However, lab results of blood and spitum cultures done shortly before the donor's death, as well as charts covering his last five admissions to the hospital, were missing from the chart. Had the chart been complete, it would have revealed that the donor had cirrhosis and a history of a number of other contraindications. Moreover, the doctor testified that apparently no one at the hospital had any responsibility to determine the suitability of eyes for transplantation.[90]

The court held that the hospital breached its duty of care to the recipients by failing to set up a procedure that would assure that a party responsible for determining the suitability of the donor would have access to all the relevant medical records of the proposed donor.[91] While liability was based on this omission, the court also could have focused on the failure to do standard tests to detect diseases.[92]

While this case clearly illustrates that negligent practices in the selection of tissue donors may result in legal liability, heart transplant cases will involve more complex considerations. Obviously, issues of practicality and the extent of the precautions used to screen out defects in donor hearts will be influenced by the need to

move quickly to retrieve the organ, and the limited time that the organ is viable outside of the body. As stated earlier, establishing causation may also be difficult, especially since the heart recipient, unlike the cornea recipient, is considerably more open to infection from all sources as a result of immunosuppressive drugs. Most cases involving transplanted cancer cells probably would not result in legal liability since it may be extremely difficult to distinguish transplanted cancer from cancer arising de novo in the recipient.[93] However, the transplant team or cardiologist treating the transplant patient may have a higher duty to detect and treat cancer in transplant recipients since clinicians are or should be "acutely aware that symptoms or signs in allograft recipients may be caused by cancer," and since early diagnosis is of paramount importance to allow curative therapy.[94] It may also be difficult to establish that the donor organ was defective since the donor's remains will no longer be available and since the donor's medical records or history may not reflect an illness that was evident in the donor at the time of organ retrieval. Another issue that will undoubtedly complicate litigation in this area is the effect of organ scarcity; litigants likely would argue over the conditions under which even known defects in organs should lead to their rejection for transplantation. This may depend on many factors, including the availability of another donor organ and the condition of the potential recipient. Finally, courts may also be unwilling to provide relief, even if a standard of care can be defined and a breach of that standard can be established, because of the causation and damages issues discussed earlier.

2. LIABILITY WITHOUT FAULT

The difficulties inherent in transplant litigation may discourage actions based upon negligence theory. However, litigation in blood products cases foreshadow the possibility that transplant providers might be sued under theories imposing liability without fault. The "strict liability" blood product cases have been argued under two theories, one based in tort law, and the other under the Uniform Commercial Code (UCC).[95] In one oft-noted opinion, Cunningham v. McNeal Memorial Hospital,[96] the Illinois Supreme Court held that the presence of the serum hepatitis virus was a defect rendering the blood unreasonably dangerous to the consumer under the strict liability theory in tort law, and therefore, imposing liability despite the hospitals' inability to detect the presence of the virus.[97] At least one decision has allowed a cause of action based upon breach of implied warranty in the transfusion of impure blood.[98]

Some cases draw a distinction between hospitals using blood, and blood banks. The Supreme Court of Colorado has held a blood bank strictly liable for injuries resulting from a blood transfusion.[99] As recently as 1981, the Supreme Court of Louisiana held a blood bank strictly liable in tort for injuries sustained by a patient who contracted hepatitis after receiving a blood transfusion. This decision, like most of the others discussed above, has since been overturned by statute.[100] The bulk of decisions, however, reject the application of strict liability and implied warranty theories to blood transfusion cases, on the basis that the provision of blood is a service and not a "sale of goods."[101]

In Perlmutter v. Beth David Hospital,[102] the court decided that providing blood to the patients of a nonprofit hospital did not constitute a sale, reasoning that a hospitalized individual seeks a course of treatment rather than a product. It also found that the patient assumed the risk of the inherent "product defect" in exchange for medical treatment. Many states have reached the Perlmutter result by legislation. After the first cases imposing liability in blood products cases were handed down, a number of states reacted by enacting legislation intended to free hospitals (and in many instances, blood banks) from liability without fault. The statutes vary somewhat in their provisions, but the Illinois statute is typical. It provides that transfusing blood or blood products is not a sale and no warranties attach, and further provides that liability may be imposed only for negligence or willful misconduct.[103]

Many state legislatures have also recognized that protection from strict liability should also be provided to persons engaged in tissue and organ procurement and transplantation. For example, a Michigan statute provides that:

> the procurement, processing, distribution, or use of whole blood plasma, blood products, blood derivatives, and other human or artificial tissues such as corneas, bones or organs, for the purpose of injecting, transfusing or transplanting any of them into the human body is declared to be for all purposes, the rendition of a service by every person, firm, or corporation participating therein and, whether or not any remuneration is paid therefore is declared not to be a sale of whole blood, plasma, blood products, blood derivatives, or other tissues, for any purpose. A warranty, expressed, implied, or otherwise, shall not attach to the activity, transaction, or occurrence. A person, firm, or corporation involved in the rendition of any such services shall not be liable as a result of

> any such activity, transaction, or occurrence, except for his or its own negligence of willful misconduct.[104]

This type of legislation effectively places the risk of defective human tissue such as hearts on the recipient, unless he or she can establish negligence on the part of a provider. Transplant providers in states with statutes like the Michigan law, therefore, cannot be held liable for defects that cannot be prevented with the use of reasonable care. Recent trends in blood transfusion case law indicate that most courts will be reluctant to imposes strict liability in organ transplant cases, even in states without such statutes. However, in the absence of a carefully worded statute or a Perlmutter type decision, there remains a chance that organ procurement centers, transplant centers and involved personnel might be held strictly liable for defects in the transplanted part.[105]

E. LEGISLATIVE APPROACHES TO THE DETERMINATION OF DEATH

The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research reported that prior to the recommendation of the Uniform Determination of Death Act, five prototype statutes were employed by legislatures. The material below discusses each of these.

1. THE KANSAS LAW

In 1970, the Kansas legislature took the first legal action in an American jurisdiction recognizing brain-based criteria for the determination of death. The Kansas statute provided alternative

"definitions" of death, one based upon traditional heart-lung functions and the other upon brain functions. It provides that:

> A person will be considered medically and legally dead if, in the opinion of a physician, based on ordinary standards of medical practice, there is the absence of spontaneous respiratory and cardiac function and, because of the disease or condition which caused, directly or indirectly, th4ese functions to cease, or because of the passage of time since these functions ceased, attempts at resuscitation are considered hopeless; and, in this event, death will have occurred at the time these functions ceases; or a person will be considered medically and legally dead, if in the opinion of a physician, based on ordinary standards of medical practice, during reasonable attempts to either maintain or restore spontaneous circulatory or respiratory function in the absence of aforesaid brain function, it appears that further attempts at resuscitation or supportive maintenance will not succeed, death will have occurred at the time when these conditions first coincide. Death is to be pronounced before artificial means of supporting respiratory and circulatory function are terminated and before any vital organ is removed for purposes of transplantation.
>
> These alternative definitions of death are to be utilized for all purposes of this state, including the trials of civil and criminal cases, any laws to the contrary notwithstanding.[106]

With slight variations, Maryland,[107] New Mexico,[108] and Virginia[109] enacted statutes patterned on the Kansas model. In 1975, Oklahoma adopted a statute drawn solely from the second alternative definition of the Kansas prototype.[109]

The President's Commission reported that the dual nature of the Kansas statute is its most troublesome feature. The alternative standards are set forth in two separate, complex paragraphs without a description of how they were to be related to the single phenomenon, death. When the statute was enacted, transplantation was very much in

the news. The two-pronged statute seems to create one definition of death for most people and another, apparently more lenient standard, for "harvesting" organs from potential donors.

2. THE CAPRON-KASS MODEL

The Capron-Kass proposal was designed to overcome the confusion over the dual death problem inherent in the Kansas statute.[111] The model statute states that:

> A person will be considered dead if in the announced opinion of a physician, based on ordinary standards of medical practice, he has experienced an irreversible cessation of respiratory and circulatory functions, or in the event that artificial means of support preclude a determination that these functions have ceased, he has experienced an irreversible cessation of total brain functions. Death will have occurred at the time when the relevant functions ceased.[112]

Seven states have adopted versions of the Capron-Kass model; and Alaska, Iowa, Louisiana and Michigan enacted the statute with only minor modifications.[113]

3. THE AMERICAN BAR ASSOCIATION PROPOSAL

The American Bar Association proposal states that:

> For all legal purposes, a human body, with irreversible cessation of total brain function, according to usual and customary standards of medical practice, shall be considered dead.[114]

Montana and Tennessee adopted the proposal verbatim.[115] Illinois used very similar language, but inserted the standard in the state's Anatomical Gift Act.[116]

The President's Commission noted that, because it ignores determination of death based on the traditional cardiopulmonary

criteria, a "single standard" statute of the ABA-type might appear to be irrelevant to most patients. To avoid this problem, several states, including California, amended the statute to permit determinations to be made based on "other usual and customary procedures"--unfortunately, without explicating these terms or their relationship to the brain-based standards. The inclusion of this second undefined alternative magnifies the "two (unrelated) deaths" problem of the Kansas statute.

4. THE UNIFORM BRAIN DEATH ACT

The Uniform Brain Death Act was recommended in 1978 by the National Conference of Commissioners on Uniform State Laws (NCCUSL). It provides that:

> For legal and medical purposes, an individual who has sustained irreversible cessation of all functioning of the brain, including the brain stem, is dead. A determination under this section must be made in accordance with reasonable medical standards.[117]

It has been adopted verbatim in Nevada,[118] and in part in West Virginia.[119] The West Virginia provision came as a partial amendment to an earlier statute on the Capron-Kass model.[120]

5. THE AMERICAN MEDICAL ASSOCIATION PROPOSAL

The President's Commission reported in 1981 that no jurisdiction had yet adopted the AMA proposal.[121] Unlike most other statutes, it contained extensive provisions to limit liability for people making or taking actions pursuant to declarations as authorized by the state.

Of the 25 statutes adopted prior to 1981 that are still on the books, 18 were based on the first four models (no state having directly followed the AMA proposal). But in many instances the statutes as enacted depart in significant ways from the prototypes; in addition to the seven states with original legislation not cut to any of the model patterns, almost all of the other 18 contain some verbal variations (from minor to major).

The President's Commission reported that, as of 1981, seven states have adopted statutes that do not closely track any of the model proposals. In 1975, Oklahoma adopted the "brain death" half of the Kansas statute, as mentioned previously, and Oregon enacted a law with alternative definitions that is much shorter than the Kansas statute.

In recent years, states have turned increasingly to nonstandard statutes. North Carolina originally adopted a rather confusing statute in 1977, incorporating both "brain-death" and "living wills" provisions. It recently substituted a somewhat clearer statute, an amalgam of the American Bar Association and Capron-Kass approaches. Its central provision reads:

> Brain death may be used as the sole basis for the determination that a person has died, particularly when brain death occurs in the presence of artificially maintained respiratory and circulatory functions.

In 1979, three states enacted idiosyncratic statutes. The provisions in Arkansas and Connecticut essentially elaborate a brain-only standard. Connecticut, like Illinois, placed its law as an amendment to the state's Uniform Anatomical Gift Act. Wyoming's law

amalgamates the basic structure of the ABA model with several features of the Uniform Brain Death Act, specifically the inclusion of explicit reference to the brain stem and the replacement of "shall be considered dead" by "is dead." Most unusually, Wyoming drew on the NCCUSL's "Comment" for additional statutory language defining brain functions as "purposeful activity of the brain as distinguished from random activity."

Finally, Florida, in 1980 became the twenty-sixth state with a statutory "definition" of death. Its statute also draws on the ABA model and Uniform Brain Death Act in only explicitly recognizing "irreversible cessation of the functioning of the entire brain," but draws on the Capron-Kass approach by implicitly acknowledging the cardiopulmonary standard. It provides that the brain-based standard is to be used "where respiratory and circulatory functions are maintained by artificial means of support so as to preclude a determination that these functions have ceased." The Florida statute also specifically requires that determinations of death be made by two physicians, including one specialist, and that the family be notified of the procedures used to determine death; the statute also draws on Sections 2 and 3 of the AMA model in insulating from liability those acting in accordance with its terms.[122]

In an attempt to bring uniformity to the area, the National Conference on Commissioners on Uniform State Laws adopted the following bill in 1980. The Act provides:

> Section 1. [Determination of Death.] An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2)

> irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards.
>
> Section 2. [Uniformity of Construction and Application.] This Act shall be applied and construed to effectuate its general purpose to make uniform the law with respect to the subject of this Act among states enacting it.
>
> Section 3. [Short Title.] This Act may be cited as the Uniform Determination of Death Act.

The Act is designed to supercede the prior model bills, and has been approved by both the AMA and the President's Commission.[123] This Act has been adopted by a number of legislatures, including Colorado and Idaho.[124]

FOOTNOTES

Section 1

1. Previously, the focus was on the use of new antibiotics and drugs that called for no new equipment but incurred principally research, development, and marketing costs. Now the emphasis is on new techniques that are usually resource intense. Examples of this trend include chemotherapy, intensive care units for burns, shock and cardiac arrest, and organ transplantation. Iglehart, The Cost and Regulation of Medical Technology: Future Policy Directions, Milbank Memorial Fund Quarterly, 25-79 (1977); Thomas, The Lives of a Cell: Notes of a Biology Watcher (1974); and Thomas, Notes of a Biology Watcher: The Technology of Medicine, 285 New England Journal of Medicine 366 (1977), cited in Evans, Health Care Technology and the Inevitability of Resource Allocation and Rationing Decisions (pts. 1 & 2), 249 Journal of the American Medical Association 2047 (1983), 249 Journal of the American Medical Association 2208 (1983); Rettig, The Changing Federal Role in Medical Technology, Technology Review 34, 34-41 (1980).

2. The bases of our emphasis on medical technology are multifaceted. Analysts argue that many actors, both within and outside of the health care system, have contributed to the rapid development and diffusion of medical technology. They suggest that hospitals compete to achieve quality and prestige in order to attract patients and physicians through the acquisition of expensive technologies, and that both the medical profession as a group and many individual physicians have encouraged increasingly sophisticated and technologically oriented specialization within medicine. In addition, some argue that physicians contribute to the process as a result of the natural desire to do as much as possible for their patients and their fear of malpractice suits, as well as their uncertainty as to what constitutes appropriate use. Analysts point most often, however, to third party payors and their policies for the reimbursement of new technologies as having the most marked affect both on the costs of care and the patterns of use of particular medical technologies. See, e.g., Evans, cited n. 1; Bunker, Fowles, Schafferzich, Evaluation of Medical Technology Strategies: Effects of Coverage and Reimbursement (pts 1 & 2), 306 New England Journal of Medicine 604 (1982), 306 New England Journal of Medicine 687 (1982); Altman, Blendon, Medical Technology: The Culprit Behind Health Care Costs? DHEW Pub. No. (PHS) 79-3216, Washington, DC: Government Printing Office, 1979; Maloney, Rogers, Medical Technology: A Different View of the Continuous Debate Over Costs, 301 New England Journal of Medicine 1413 (1979); Bennett, Technology as a Shaping Force, 106 Daedalus 125 (1977); Feldstein, Taylor, The Rapid Rise of Hospital Costs, Washington, DC: Government Printing Office, (1977); Waldman, Effect of Changing Technology on Hospital Costs, 35 Social Security Bulletin 28 (1972).

3. See, for example, Rettig, supra, n. 1.

4. Id.

5. See n. 87, infra.

6. Faced with the necessity of controlling Medicare spending, both Congress and the Executive branches are considering methods aimed at controlling the use or reimbursement of certain medical procedures and techniques. If implemented, such policies may significantly affect the manner and extent to which the federal government will pay for health care. Until recently, for example, the major reason for excluding a medical procedure from Medicare reimbursement was that it had not been demonstrated to be safe and effective. Knox, Heart Transplants: To Pay or Not to Pay? 206 Science 570 (1980). The statute governing Medicare reimbursement requires that treatments be deemed "reasonable and necessary" before they will be reimbursed under Medicare. 42 U.S.C. Section 1395y(a)(1). The phrase is not defined either in the Social Security Act or the Regulations. Breeden v. Weinberger, 277 F. Supp. 734, 737 (M.D. La. 1974).

   In 1980, however, then Secretary of the Department of Health and Human Services (DHHS), Patricia Roberts Harris, announced that new medical technologies, starting with heart transplantation, would have to be evaluated not only on the basis of their medical efficacy and safety, but also on the basis of their "social consequences" before the government would finance their wide distribution and utilization. This new criterion was defined to include its cost-effectiveness, cost-benefit ratios, as well as its legal and ethical implications, and long-term effects on society. This concern with cost-effectiveness continues to be felt in the present administration.

7. See, Merrikin and Overcast, An Antitrust Primer: Implications of Antitrust Law for the Regulation of Heart Transplantation, Battelle Human Affairs Research Cetners, 1983 (unpublished manuscript).

8. See n. 87, infra.

9. Id.

10. National Health Planning and Resources Development Act of 1974, 42 U.S.C. Sections 300k-300t (1976).

11. See, for example, Caminisch, The Right to Health Care: A Contractual Approach, 62 Soundings 293 (1979); and Childress, Who Shall Live When Not All can Live? 43 Soundings 339 (1970).

12. Enthoven, Health Plan xv-xvii, 13-32 (1980).

13. Gibson & Waldo, National Health Expenditures, 1980, 3 Health Care Financing Review 1 (1981). In 1980, health expenditures amount to about $1.607 per person. About 42% of that that amount ($450) came from public funds. Total health care expenditures for 1980 were approximately $247 billion, or roughly 9.4% of the gross national product. See also, Marmor, Feder & Holahan, Introduction, in National Health Insurance: Conflicting Goals and Policy Choices 1, 7-12 (J. Feder, J. Holahan & T. Marmor eds. 1980).

14. Schwartz, We Need to Ration Medicine, Newsweek, February 8, 1983.

15. Becker, Finite Resources and Medical Triage, 66 American Journal of Medicine 549 (1979); Martin, Donaldson, London, Peterson, Cotton, Inputs Into Coronary Care During 30 Years: A Cost-effectiveness StudY, 81 Annals of Internal Medicine 289 (1974); Rescher, The Allocation of Exotic Medical Lifesaving Therapy, 79 Ethics 173 (1969).

16. Schelling, The life you save may be your own. In Chase (Ed.), Problems in public expenditure analysis 127 (1968).

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18. Fuchs, Who shall Live? Health, economics, and social choice (1974); Weinstein & Stason, Hypertension: A policy perspective (1976); Weinstein, Stason, Foundations of Cost-effectiveness Analysis for Health and Medical Practices, 296 New England Journal of Medicine 716 (1977); Weinstein, Fineberg, Elstein, Frazier, Heuhauser, Neutra & McNeil, Clinical decision analysis (1980); Stason & Weinstein, Allocation of Resources to Manage Hypertension, 296 New England Journal of Medicine 732 (1977); Weinstein, Estrogen Use in Postmenopausal Women -- Costs, Risks and Benefits, 303 New England Journal of Medicine 308 (1980).

19. Weinstein & Stason, Foundations of Cost-effectiveness Analysis for Health and Medical Practices, 296 New England Journal of Medicine 716 (1977).

20. Mechanic, The Growth of Medical Technology and Bureaucracy: Implications for Health Care, 55 Milbank Memorial Fund Quarterly 61 (1977).

21. Mechanic, Medical sociology (1978); Aday & Anderson, Development of indices of access to medical care (1975).

22. Childress, Rationing of medical treatment. In Reich (Ed.), Encyclopedia of biomedical ethics (1979).

23. Blumstein, Constitutional and legal constraints on the rationing of medical resources. Paper prepared for the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. (1981).

24. Evans, Blagg, Bryan Jr., Implications for Health Care Policy: A Social and Demographic Profile of Hemodialysis Patients in the United States, 245 Journal of the American Medical Association 487 (1981); Fox, and Swazey, The Courage to Fail, (1974).

25. Evans, Blagg, Bryan Jr., n. 24, supra.; Abram, Dilemmas of Medical Progress, 3 Psychiatric Medicine 51 (1972); Katz, and Proctor, Social-Psychological Characteristics of Patients Receiving Hemodialysis Treatment for Chronic Renal Failure: Report of a Questionnaire Study of Dialysis Centers During 1967. The Kidney Disease Program, Division of Chronic Disease Programs, Regional Medical Programs Service, Health Services and Mental Health Administration, Public Health Service, U.S. Department of Health, Education, and Welfare, 1969.

26. Newman, Health Care Financing Administration, Medicare Program: Solicitation of Hospitals and Medical Centers to Participate in a Study of Heart Transplants, 46 Federal Register 7072 (1981); Pennock, Oyer, Reitz, Jamieson, Bieber, Wallwork, Stinson, Shumway, Cardiac Transplantation in Perspective for the Future: Survival, Complications, Rehabilitation, and Cost, 83 Journal of Thoracic Cardiovascular Surgery 168 (1982); Copeland, Salomon, Mammana, Siroky, Larson, Cardiac Transplantation: A Two-year Experience, 1(1) Heart Transplantation 67 (1981); Oyer, Stinson, Reitz, Bieber, Jamieson, Shumway, Cardiac Transplantation: 1980, 13 Transplant Proceedings 199 (1981).

27. Evans, Blagg, Bryan Jr., n. 24, supra.

28. Peterson v. Greenville, 373 U.S. 244 (1963); Lombard v. Louisiana, 373 U.S. 267 (1963); Burton v. Wilmington Parking Authority, 365 U.S. 715 (1961).

29. The various certificate of need (CON) laws are the most important examine of the ability of the government to impose constraints on the private sector. See, Havighurst, Regulation of Health Facilities and Services by "Certificate of Need," 59 Virginia Law Review 1143 (1973); Salkever & Bice, The Impact of Certificate-of-Need Controls on Hospital Investment, 54 Milbank Memorial Fund Quarterly: Health and Society 185 (1976).

30. Whalen v. Roe, 429 U.S. 589 (1977), upholding a statute that required the recording of the identity of persons to whom prescriptions were issued.

31. As part of a general cost containment strategy necessitated by the lack of public funds available for health care, a number of

states have reduced the number of days of hospitalization covered under their Medicaid programs. Jennings v. Alexander, 518 F. Supp. 877 (M.D. Tenn. 1981), holding that a state's proposed reduction of Medicaid benefits does not violate federal law.

32. While the equal protection clause does not apply directly to federal law, the Supreme Court has construed the due process clause of the fifth amendment to mean that the federal government has an obligation to ensure equal protection of the laws. Bolling v. Sharpe, 347 U.S. 497 (1954).

33. Ely, Legislative and Administrative Motivation in Constitutional Law, 79 Yale Law Journal 1205, 1224 (1970).

34. McGowan v. Maryland, 366 U.S. 420, 425-426 (1961).

35. Minnesota v. Clover Leaf Creamery Company, 449 U.S. 456 (1981).

36. In the last 40 years, the Supreme Court has applied this traditional test once to strike down state legislation, and the Court subsequently overruled that case. New Orleans v. Dukes, 427 U.S. 297 (1976) (overruling Morey v. Doud, 354 U.S. 457 (1957).

37. Dandridge v. Williams, 397 U.S. 471, 487 (1970).

38. See Note 60, Infra.

39. San Antonio Independent School District v. Rodriguez, 411 U.S. 1 (1973).

40. Dandridge v. Williams, 397 U.S. 471 (1970).

41. Lindsey v. Normet, 405 U.S. 56 (1972).

42. Harris v. McRae, 448 U.S. 297 (1980); Maher v. Roe, 432 U.S. 464 (1977).

43. Loving v. Virginia, 388 U.S. 1 (1967).

44. Bolling v. Sharpe, 347 U.S. 497 (1954); McLaughlin v. Florida, 379 U.S. 184 (1964).

45. Graham v. Richardson, 403 U.S. 365 (1971).

46. The use of racially based criteria for "benign" purposes may receive less strict scrutiny. See, Fullilove v. Klutznick, 448 U.S. 448 (1980); Regents of the University of California v. Bakke, 438 U.S. 265 (1978).

47. Wengler v. Druggists Mutual Insurance Company, 446 U.S. 142 (1980); Massachusetts Board of Retirement v. Murgia, 427 U.S. 307 (1976).

48. Rostker v. Goldberg, 101 S. Ct. 2646 (1981).

49. Frontiero v. Richardson, 411 U.S. 677 (1973).

50. 429 U.S. 190 (1976).

51. 429 U.S. 190, 197 (1976).

52. 426 U.S. 229 (1976).

53. 442 U.S. 256 (1979).

54. 442 U.S. 256, 279 (1979).

55. United States v. Classic, 313 U.S. 299 (1941).

56. Federal law, 42 U.S.C. Section 1983 (1976), allows a cause of action against those who, acting under color of state law, deprive the person of his or her constitutional rights.

57. See, Polk County v. Dodson, 102 S. Ct. 445 (1981), and Shelley v. Kraemer, 334 U.S. 1 (1948).

58. Pasadena City Board of Education v. Spangler, 427 U.S. 424 (1976); Jackson v. Metropolitan Edison Company, 419 U.S. 345 (1974); Moose Lodge No. 107 v. Irvis, 407 U.S. 163 (1972).

59. Burton v. Wilmington Parking Authority, 365 U.S. 715 (1961).

60. Marsh v. Alabama, 326 U.S. 501 (1946).

61. Note 13, Supra.

62. Flagg Brothers v. Brooks, 436 U.S. 149 (1978).

63. See, Board of Regents v. Roth, 408 U.S. 564, 570-571 (1972).

64. Note 18, Supra at 577.

65. See Note 18, Supra.

66. Paul v. Davis, 424 U.S. 693, 711 (1976).

67. See Note 18, Supra at 576.

68. See Note 21, Supra.

69. See Note 21, Supra at 711-712.

70. 442 U.S. 1 (1979).

71. 442 U.S. at 9.

72. 442 U.S. at 9, citing Friendly, Some Kind of Hearing, 123 University of Pennslyvania Law Review 1267 (1975).

73. Little v. Streater, 452 U.S. 1, 5 (1981).

74. See Note 28, Supra; Board of Curators v. Horowitz, 435 U.S. 78 (1978).

75. Parratt v. Taylor, 451 U.S. 527 (1981); Ingraham v. Wright, 430 U.S. 651 (1977).

76. 424 U.S. 319 (1976).

77. Note 33, Supra at 335.

78. Holmes v. New York City Housing Authority, 398 F.2d 262 (2d Cir. 1968).

79. Hornsby v. Allen, 326 F.2d 605 (5th Cir. 1964).

80. Under the entitlements approach, the existence of an entitlement is a prerequisite for the inquiry. Without such an entitlement, procedural due process requirements simply do not apply. Thus, there would be no justification for requiring specific standards unless an entitlement already existed.

81. Blumstein, Rationing Medical Resources: A Constitutional, Legal, and Policy Analysis, 59 Texas Law Review 1345 (1981).

82. Caplan, Kidneys, Ethics, and Politics: Policy Lessons of the ESRD Experience, 6 Journal of Health Politics, Policy, and Law 488 (1981).

83. G. Calabresi & P. Bobbitt, Tragic Choices 57 (1978).

84. J. Katz & A. Capron, Catastrophic Diseases: Who Decides What? 3 (1975).

85. Williamson v. Lee Optical, 348 U.S. 483 (1955); North Dakota State Board of Pharmacy v. Snyder's Drug Stores, Inc., 414 U.S. 156 (1973); Ferguson v. Skrupa, 372 U.S. 726 (1963).

86. Roe v. Wade, 410 U.S. 113 (1973).

87. Harris v. McRae, 448 U.S. 297, 312 (1980).

88. Kennedy, The Responsibilities of the Government: A Legislative Viewpoint, in Implications of Guaranteeing Medical Care 103 (J. Perpich, ed. 1975).

89. Harris v. McRae, 448 U.S. 297 (1980); Estelle v. Gamble, 429 U.S. 97 (1976).

90. Note 46, Supra. The nature of the interest recognized in Roe was an individual's freedom to make certain kinds of basic decisions without excessive governmental compulsion.

91. See, Boddie v. Connecticut, 401 U.S. 371 (1971) (state monopolization of the procedures for legally dissolving a marriage); Little v. Streater, 452 U.S. 1 (1981) (state obligation to provide access to blood test to establish paternity).

92. United States v. Kras, 409 U.S. 434, 444-445 (1973).

93. San Antonio Independent School District v. Rodriguez, 411 U.S. 1 (1973).

94. 429 U.S. 97 (1976).

95. 429 U.S. 97, 103 (1976).

96. 429 U.S. 97, 103 (1976).

97. 430 U.S. 651 (1977).

98. 430 U.S. 651, 669 (1977).

Section 2

1. Due to the limited availability of donor organs, limited fiscal and personnel-related resources, and its still quasi-experimental nature, heart transplantation is, for the moment, being carried out only on a limited scale. Patient demand for the procedure will probably increase as the success ratio improves and the procedure moves into the realm of accepted therapy. Despite the limitations imposed by organ shortages and immunosuppressive techniques, and the very high cost of heart transplantation, it is likely that the medical profession will seek to answer the call, because physicians traditionally have taken the attitude that if a procedure helps a patient it should not be withheld. See Christopherson, L., Heart Transplants, 12 The Hastings Center Report 18 21, (1982). For a direct statement of this view by a physician, see, Erich H. Loewy, M.D. (Letter to the Editor), 303 New England Journal of Medicine 288 (1980).

   The types of limited reimbursement plans discussed here have been suggested as viable policy alternatives. In a 21 January consensus memo written by the NHLBI (National Heart, Lung and Blood Institute) Deputy Director Peter Frommer, the committee (set up to look at heart transplants) recommended that Medicare pay for heart transplants at Stanford and other U.S. centers that meet comparable standards of expertise, resources, and commitment, and for patients who fit the Stanford selection criteria or acceptable equivalents. They also identified several

dangers that they stated must be forcefully resisted or carefully avoided" though they did not say how. These included proliferation of other centers not as well equipped as Stanford and loosening of patient selection criteria.

Currently, however, there is no provision that specifically permits selective reimbursement. Indeed, the relevant statute provides that Medicare may not discriminate between any institution, agency or person qualified to participate and undertaking to provide services under the Medicare program. 42 U.S.C. Sec. 1395a.

2. Blumstein, Rationing Medical Resources: A Constitutional, Legal, and Policy Analysis, 59 Texas Law Review 1345, 1388 (1981).

3. The court's broad view of the commerce power would probably permit federal regulation of heart transplantations. The power of the federal government to regulate interstate commerce is extensive. See Perez v. United States, 402 U.S. 146 (1971); Heart of Atlanta Motel v. United States, 379 U.S. 241 (1964); Wickard v. Filburn, 317 U.S. 111 (1942); United States v. Darby, 312 U.S. 100 (1941). It is apparently only subject to the limitation that federal regulation may not directly and substantially "displace the State's freedom to structure integral operations in areas of traditional government functions." National League of Cities v. Usery, 426 U.S. 833, 852 (1976) (Tenth Amendment prohibits the federal government from subjecting state and local governments to the minimum wage and overtime standards of the Fair Labor Standards Act). This limitation on the federal commerce power has since been given a narrow interpretation by the Supreme Court. See Federal Regulatory Commission v. Mississippi, 50 U.S.L.W. 4566 (U.S. June 1, 1982); United Transportation Union v. Long Island Railroad, 50 U.S.L.W. 4315 (U.S. Mar. 24, 1982); Hodel v. Virginia Surface Min. & Recl. Ass'n., 452 U.S. 264 (1981); Fitzpatrick v. Bitzer, 427 U.S. 445 (1976). Recent limitations on Usery indicate that the 10th amendment will probably not protect any exercise of state powers from a federal preempting statute that is a legitimate incident of federal regulation of interstate commerce. See discussion in Kissam, Government Policy Toward Medical Accreditation and Certification, 1983 Wisconsin Law Review 1, 76-88; and Wing and Silton, Constitutional Authority for Extending Federal Control Over the Delivery of Health Care, 57 Duke Law Journal 1423 (1979). State regulation of heart transplantation would be justified under the police power as an aspect of state protection of the health of persons in its confines. See, e.g., Roe v. Wade, 410 U.S. 113 (1973).

4. Blumstein, supra, n. 88, at p. 1388.

5. Id. at 1388, citing Planned Parenthood of Central Missouri v. Danforth, 428 U.S. 52, 75-79 (1976), and Carey v. Population Services International, 431 U.S. 678 (1977).

6. Carey v. Population Services International, 431 U.S. 678, 688 (1977). The Court in Carey explained that "this is not because there is an independent fundamental right of access, but because this access is essential to the exercise of the constitutionally protected right of decision." Id.

7. Maher v. Roe, 432 U.S. 464 (1977); Harris v. McCrae, 100 S.Ct. 2671 (1980).

8. See, e.g., 432 U.S. at 474.

9. 432 U.S. at 474 n. 5.

10. Id. at 475 n. 6, quoting Buckley v. Valeo, 424 U.S. 1, 94 (1976).

11. Id. at 473, quoting Planned Parenthood v. Danforth, 428 U.S. 52, 70-71 n. 11 (1976).

12. Id. at 474.

13. Id. at 474-8.

14. Frontiero v. Richardson, 411 U.S. 677 (1973).

15. See, e.g., Whalen v. Roe, 429 U.S. 589 (1979); Rutherford v. United States, 442 U.S. 544 (1979); Roe v. Wade, 410 U.S. 113 (1973); People v. Privitera, 23 Cal.3d 697 (1979); In re Quinlan, 155 N.J. Super 593 (1977); Andrews v. Ballard, 498 F. Supp. 1038 (S.D. Tex. 1980).

16. Andrews v. Ballard, 498 F. Supp. 1038 (S.D. Tex. 1980).

17. Id. at 1053.

18. Id. at 1052.

19. Id. at 1054.

20. Id. at 1056.

21. Id. at 1057. Having thus considered and rejected all of the state's justifications for the statute and rules, Judge McDonald entered a declaratory judgment in favor of the plaintiffs.

22. Obviously, different forms of regulation would be precipitated by different governmental concerns. It is beyond the scope of this section to exhaustively analyze different forms of regulation and their possible objectives, particularly since the possibility of (and hence the ultimate form of) regulation is speculative. However, we can discuss several possible justifications for regulation of heart transplantation and other forms of innovative medical therapy that have appeared in health care discussions,

and the importance that such interests have been accorded in the courts. Note that these interests do not actually fall into entirely discrete compartments. Rather, the interests intertwine in many ways and at different points.

23. See n. 8, supra.

24. 410 U.S. 113, 162-63 (1973).

25. Whalen v. Roe, 429 U.S. 589 (1977) ("It is of course well settled that the state has broad powers in regulating the administration of drugs by the health professions," Id. at 603); Williamson v. Lee Optical, Inc., 348 U.S. 483, 490 (1955); Ice v. Indiana State Bd. of Dental Examiners, 240 Ind. 82, 84-85, 161 N.E.2d 171, 172-173 (1959): Campbell v. State, 12 Wash.2d 459, 462-63, 122 P.2d 458, 461-62 (1942).

26. Andrews v. Ballard, 498 F. Supp. 1038, 1052 (S.D. Tex. 1980).

27. Id., citing Shelton v. Tucker, 364 U.S. 479, 488 (1960).

28. See discussion ns. 49-67 supra.

29. In Roe v. Wade, the court noted:

> (One reason for the adoption of the criminal abortion laws was the concern) with abortion as a medical procedure. When most (laws) were enacted, the procedure was a hazardous one for the woman. (Modern) medical techniques have altered this situation. (Medical data indicate) that abortion in early pregnancy, that is, prior to the end of the first trimester, although not without its risk, is now relatively safe. (But) important state interests in the area of health and medical standards do remain.
>
> The State has a legitimate interest in seeing to it that abortion, like any other medical procedure, is performed under circumstances that ensure maximum safety for the patient." 410 U.S. 131; 149-50 (emphasis added).

The Court found that the state could safeguard the interests in maternal health by requiring all abortions to be performed at licensed institutions, and by prohibiting the performance of abortions by unlicensed persons. These same interests in safety and efficacy would apply if the right to decide to undergo a particular form of treatment is recognized, and thus indicate several ways in which the health care decisional right could be legitimately circumscribed by the state.

In addition to permitting such uniform state regulation of abortion during all stages of pregnancy, the Court also

recognized that the state interests in protecting the pregnant woman's health and the potential life of the fetus become more compelling as pregnancy progresses. The Court therefore allowed increasing regulation of the abortion procedure according to a rough trimester schedule. For approximately the first trimester, the Court stated that the abortion decision and its effectuation must be left to the medical judgment of the pregnant woman's attending physician. After this period (i.e., during the second and third trimesters), the state could legitimately regulate the abortion procedure in ways that are reasonably related to maternal health. For the stage subsequent to the point at which the fetus becomes viable (identified as roughly the beginning of the third trimester), the state can regulate and even proscribe abortion except where abortion is necessary for the preservation of the life or health of the pregnant woman. Id. at 164-65.

The Court's recognition of the fact that the balance between individual and state interests could shift according to the progression of pregnancy has spurred similar balancing arguments with regard to recognition of the privacy right and limitations on the state's ability to regulate the availability of certain cancer treatments to terminal patients. Several plaintiffs and commentators have reasoned that while the state's interest in the safety and efficacy of drugs such as laetrile permit it to regulate and even prohibit their use by non-terminal patients, the fact that the regulations apply to drug use by terminal patients render them overbroad. They argue that as the disease progresses and death becomes imminent, the state's interests in the patient's health are correspondingly decreased. This theory and its counter arguments are discussed in Comment, Picking Your Poison: The Drug Efficacy Requirement and the Right of Privacy, 25 U.C.L.A. Law Review 547, 577, 609-613 (1978).

Such an argument could also be made if the state tried to regulate heart transplantation. Because the Court seemingly recognizes that the state may at all stages protect health by requiring licensure of practitioners, it is doubtful that the patient could assert that his lessened life chances mandate lessened control over the provider's qualifications. If, however, the state chose to ban heart transplantation on the ground that it was unsafe or inefficacious, such an argument might be raised. The heart transplant patient typically may only have a very short amount of time to live if he or she does not receive a transplant; transplantation is a "last ditch" effort to prolong life. It could be argued that the state interest in the preserving the health of the patient is lessened when the patient is terminal, and the procedure he or she wishes to undergo cannot, therefore, worsen his or her condition. When the individual's right to decide to seek out a heart transplantation is balanced against the state's interest in preservation of life and health, arguably the balance may weigh more heavily in favor of the individual than would be the case if the patient were not

terminally ill. See, Comment, Picking Your Poison: The Drug Efficacy Requirement and the Right of Privacy, 25 U.C.L.A. Law Review 577, 611 (1978):

> State interest in the protection of the individual from non-efficacious drugs arguably wanes when the individual's choice is informed and effective alternatives do not exist.

The author proceeds to note, however, that other state interests may justify regulation:

> Nevertheless, in situations where no proven medical treatment exists and considerations of relative efficacy are therefore immaterial, the state retains an interest in the prevention of economic exploitation. Although this interest, without more, would probably not satisfy strict judicial scrutiny in situations where the individual's choice is uninformed, under duress, or undue influence, or without full appreciation of the complexities present in the decision, protection of the individual is deserving of considerable weight in the balancing. Id.

30. The data do not support this, only the theory does.

31. Various courts, have however, indicated that the state and federal governments have an important, if not compelling interest in promoting efficient use of hospital resources and in controlling health care costs. See, e.g., North Carolina ex rel. Morrow v. Califano, 445 F. Supp. 532 (E.D. N.C. 1977), aff'd mem., 435 U.S. 962 (1978); Association of American Physicians and Surgeons v. Weinberger, 395 F. Supp. 125 (N.D. Ill.), aff'd mem., 423 U.S. 975 (1975).

32. See, e.g., Annas, Allocation of Artificial Hearts in the Year 2001: Minerva v. National Health Agency, 3 American Journal of Law & Medicine 59, 61 (1977).

33. For an analysis of the economic costs of heart transplantation, see, Evans, Economic and Social Costs of Heart Transplantation, 1 Heart Transplantation 243 (1982).

In a recent article, Lois Christopherson noted some of the current funding mechanisms, and the problems associated with paying for heart transplantation. She noted that the federal government has been the primary source of funding for research and development at some transplant centers and has often met, through clinical research monies, the costs of post-transplant medical care not covered by third party payors. Payment for hospitalization required prior to transplantation has been made variously by insurance plans, Medicaid, or patients and families, but has also posed the greatest hurdle for some potential recipients. Whether transplantation is a covered service or an

exclusion (usually because it is deemed "experimental") varies among insurance companies and policies, as well as from state to state. Some insurance policies exclude transplantation; others provide payment, but only to the limits of a holder's coverage. While improved transplant results may well make it more difficult for a policy to exclude transplantation as an experimental procedure, the costs and length of hospitalization will still, in effect, exclude persons with limited policies. Even if transplant-related insurance coverage is available, the patient and his or her family may lack the personal resources or the community fund-raising support needed to meet to costs of travel to a distant transplant center and living expenses for as long as a year. Christopherson, Heart Transplants, 12 The Hastings Center Report 18-20 (1982).

34. 432 U.S. 464 (1977).

35. 100 S.Ct 2671 (1980).

36. Id. at 469. In this and the Harris opinion, the Court firmly rejected any notion that the government has any duty to provide access to medical care for anyone. Under the liberal leadership of Chief Justice Earl Warren, the Supreme Court tentatively advanced the idea that there was a fundamental right to have certain basic needs fulfilled, and that wealth inequalities would be closely scrutinized by the federal courts under the doctrines of equal protection or substantive due process. The first of the "affirmative funding" cases arose in the criminal justice context. In cases such as Griffin v. Illinois, 351 U.S. 12 (1956) and Douglas v. California, 372 U.S. 353 (1963), the Court held that the Equal Protection clause requires states that allow appellate review of criminal convictions to provide indigent defendants with trial transcripts and appellate counsel. This doctrine was extended to include a duty for the government to pay for court costs and other incidental expenses involved in a divorce proceeding, Boddie v. Connecticut, 401 U.S. 271 (1971), and a duty to pay for a blood test in a paternity proceeding, Little v. Streater, 101 S.Ct. 67, (1981).

In Maher v. Roe, however, the Supreme Court emphasized that the right of access cases would not be applied in the medical care context. Writing for the majority, Justice Powell distinguished the narrow range of cases in which the Court will impose an affirmative funding obligation on the government. As Blumstein notes, the Court found three characteristics important in imposing an affirmative funding obligation. They were: (1) the importance of the services and their constitutional connections; (2) the degree of state monopolization of access to them; and (3) the element of total deprivation based on lack of funds. Justice Powell distinguished the abortion cases from the prior cases because the state had made no attempt to monopolize the means for terminating pregnancies. As Blumstein noted, ". . . unless the

government's control over a medical resource becomes so absolute that an analogy to the court system or criminal justice system becomes appropriate, it seems clear that the court is unlikely to conclude that individuals have an entitlement under due process to governmentally provided health services of any sort." Blumstein, J., Constitutional and Legal Constraints on the Rationing of Scarce Medical Resources," Paper prepared for the President's Commission for the Study of Ethical Problems in Medicine and Biomedical Research, October, 1981, p. 35.

37. 432 U.S. 464, 473-4.

38. 410 U.S. 113 (1973).

39. 100 S.Ct 2671, 2688.

40. Blumstein, cited n. 46, supra.

41. In Maher, the plaintiffs claimed that the government's funding of childbirth expenses but not abortion expenses, burdened their freedom to choose abortion because childbirth was made the more attractive alternative. 432 U.S. at 474. The claim was a denial of equal protection because the state's creation of two classes of pregnant women -- those who would bear children, and those who would abort -- and the extension of funding for only one of these groups, infringed the fundamental right to decide whether to abort. Id. at 469-74. As the Court stated, however, the right to be free from unduly burdensome interference with the exercise of a constitutional right "implies no limitation on the authority of the state to make a value judgment favoring childbirth over abortion, and to implement that judgment in the allocation of public funds." Id. at 474.

Although the "basic difference between direct state interference with a protected activity, and state encouragement on an alternative activity consonant with legislative policy," Id. at 475, does not negate all constitutional limitations on funding decisions, it does mean that a state need not show a compelling state interest for its policy choice to favor the exercise of a constitutional right in one direction rather than another. Several limitations on funding discretion are implicitly recognized in Maher and Harris, however. First, the state cannot condition a benefit that it is not otherwise obligated to provide on exercising a constitutional right in a certain direction, unless that exercise is the very purpose of the funding or benefit, or could otherwise be required by the state. Second, it may not coerce a person into exercising a particular right a particular way. Although dissenters in both cases argued that withdrawal of Medicaid funds from abortion coerced women out of their right to abort, (see 432 U.S. at 483, Brennan, J., dissenting), the provision of financial support, incentives, or rewards will seldom amount to coercion, as Maher makes clear.

A final limitation of the use of government funding to favor the exercise of a constitutional right in a particular direction may be found in the purpose of the funding. Although legislative motivation is difficult to ascertain, and invalidation on these grounds presents problems, a racially discriminatory or religious motivation would clearly invalidate government refusal of funding for a particular type of treatment, See, e.g., Epperson v. Arkansas, 393 U.S. 97 (1968).

42. U.S. Constitution, Article 1, §8.

43. Health was traditionally viewed as a matter exclusively in the province of individual states. In Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1 (1824), Justice Marshall stated in dicta that "health laws . . . are component parts . . . of that immense mass of legislation, which embraces everything within the territory of a state, not surrendered to the general government. Id. at 203.

44. Wing and Silton, Constitutional Authority for Extending Federal Control Over the Delivery of Health Care, 57 North Carolina Law Review 1423, 1441 (1979).

45. See, e.g., Massachusetts v. Mellon, 262 U.S. 447, 480 (1923). But see U.S. v. Butler, 297 U.S. 1 (1936), where the Court held that a condition attached to the Agricultural Adjustment Act was a "scheme for purchasing with federal funds submission to federal regulation." Id. at 72. In later cases, however, the Court, while citing the Butler coercion limitation have avoided finding coercion. See, Oklahoma v. U.S. Civil Service Commission, 330 U.S. 127 (1947); Helvering v. Davis, 301 U.S. 619 (1937); Steward Machine Co. v. Davis, 301 U.S. 548 (1937); see also Comment, The Federal Conditional Spending Power: A Search for Limits, 70 Northwestern Law Review 93, 97-98 (1975).

46. See Comment, cited n. 45, supra.

47. Even here the courts have given the federal government wide latitude to impose conditions. In North Carolina ex rel Morrow v. Califano, 445 F. Supp 532 (E.D.N.C. 1977), aff'd mem, 435 U.S. 962 (1978), a federal district court upheld the constitutionality of federal health legislation that required states to enact certificate of need laws as a condition on the receipt of federal funds for health planning and for other public health programs. The Court found the measure not to be coercive despite the challenge finding an estimated loss to North Carolina of $50 million in federal monies, Id. at 535, and despite the fact that North Carolina would have to amend its constitution in order to comply with the federal law. But cf. Note, Taking Federalism Seriously: Limiting State Acceptance of National Grants, 90 Yale Law Journal 1694 (1981) (proposing a zone of state sovereignty that would be immune from federal influence, including conditions on grants.

48. Wing and Silton, Constitutional Authority for Extending Federal Control Over the Delivery of Health Care, 57 North Carolina Law Review 1423, 1443 (1979).

49. See, e.g., 42 U.S.C. Section 2000d et seq (1971); Family Education Rights and Privacy Act of 1974, 20 U.S.C. 232 (9) (1975); Rehabilitation Act of 1973, 29 U.S. C. Section Section 701-94 (1973).

50. In Rasulis v. Weinberger, 502 F.2d, 1006 (7th Cir. 1974), the court rejected a constitutional challenge to a regulation establishing professional standards for therapists participating in Medicaid and Medicare, relying heavily on the finding that the regulation "merely provides standards for the dispensation of Federal funds. The economic incentive of participation in the Medicare Program does not constitute coercion or control." Id. at 1010, citing Steward Machine Co., v. Davis, 301 U.S. 548 (1937).

51. See Comment, cited n. 45 at 305 (5th Amendment, due process clause may require such a reasonable relationship).

52. Id. at 309.

53. To cite a current example, only services funded by government programs are subject to PSRO and utilization review requirements of Medicaid and Medicare. 42 U.S.C. Section 1320a 1 (1972).

54. See, e.g., Assn. of American Physicians and Surgeons v. Weinberger, 395 F. Supp 125 (N.D. Ill., 1975), aff'd mem, 423 U.S. 975 (1975). (Statutory purpose of controlling governmental health and avoiding overutilization care spending is within the competency of the federal government.) Id. at 140.

55. See, e.g., Rasulis v. Weinberger, 502 F.2d 1006 (7th Cir. 1979); AMA v. Weinberger, 395 F. Supp. 515 (N.D. Ill, 1975), aff'd mem, 423 U.S. 975 (1975).

56. See the discussion of unconstitutional conditions in Nyberg v. City of Virginia, 677 F.2d 754, U.S. app. pending, 81-1782, filed 3/26/82.

57. Maher v. Roe, 432 U.S. 464, 474 (1977).

58. See, e.g., Nyberg v. City of Virginia, 667 F.2d 754, U.S. app. pending 81-1782 filed 3/26/82 (city could not constitutionally prohibit staff physicians from performing abortions for paying patients at sole hospital in community). In the Nyberg case, the court noted that:

> ". . . the City of Virginia and the Hospital Commission attempt to do more than simply deny governmental funding for

> abortions. If the resolution is effective, then no woman could obtain an abortion in the city hospital unless her life was endangered. Thus, the City attempts to eliminate access to abortion services at the sole hospital in the City of Virginia." 667 F.2d at 757.

This the court found to be a substantial burden on the woman's decision to have an abortion:

> Because of the prohibition on the use of the sole facility in the city for abortions, a woman is required to travel to another community. In so doing, the government is forcing the woman to take additional risks. She may not be allowed to be treated by her private physician at another hospital located in a different community; the likelihood exists that the doctor will probably not have staff privileges.
>
> The inability to rely on her own physician's services raises further complications. The woman's own physician would possess familiarity with the woman's background and needs; he would be in the best position to exercise the professional judgment necessary to determine whether abortion in a particular case would be advisable. Id.

A funding limitation would result in the same type of burdening as that pointed to here. For example, if a hospital was told not to do transplants as a condition of federal funding, a particular transplant candidate might have to travel farther, incur higher costs, etc.. It could also reduce her chance of getting treatment at any center because such a condition might reduce the total number of transplants that could be performed.

59. For discussions of the doctrine, see Note, Unconstitutional Conditions, 73 Harvard Law Review 1995 (1960); Comment, Another Look at Unconstitutional Conditions, 117 University of Pennsylvania Law Review 144 (1968); Note, Committee to Defend Reproductive Rights v. Myers: Abortion Restrictions as an Unconstitutional Condition, 70 California Law Review 978 (1982).

Section 3

1. Proger, Phillip A., "An Antitrust Primer," 1-25, p. 1, in Proger, Phillip A., ed., Antitrust in the Health Care Field (1979) (hereinafter cited as "Proger").

2. Id.

3. Conflict of interest is the core problem that much of antitrust law addresses. Critical judgments are often made by those having

a direct financial stake in the outcome. Self regulation of any type of service can limit competition among the persons who participate in that system. Moreover, private control can be used to stifle competition from persons outside the controlling group in order to exclude potential competitors.

4. United States v. Topco Associates, 405 U.S. 596 (1972).

5. 15 U.S.C. Section 1 (1976).

6. 15 U.S.C. Section 2 (1976).

7. 15 U.S.C. Section 45 (1976).

8. The courts have held that this language encompasses not only Sherman and Clayton Act violations, but also actions that are contrary to the spirit of the federal antitrust laws.

9. Unlike Sherman Act cases, the FTC actually defines unfair methods of competition and unfair or deceptive acts or practices.

10. Federal Trade Commission v. Brown Shoe Co., 384 U.S. 315 (1966). It will not have significance in this paper since it applies only to restraints involving goods or commodities, not to those involving services, such as transplantation procedures.

11. See National Society of Professional Engineers v. United States, 435 U.S. 679, 688-90 (1978); United States v. Topco Association, 405 U.S. 596, 606-07 (1972); Chicago Board of Trade v. United States, 246 U.S. 231, 238 (1918).

12. See National Society of Professional Engineers v. United States, 435 U.S. 679, 691, n. 17 (1978); Continental T.V. v. GTE Sylvania, Inc., 433 U.S. 36, 49 (1977); Appalachian Coals Inc. v. United States, 228 U.S. 344, 371 (1933); Chicago Board of Trade v. United States 246 U.S. 231, (1918).

13. In a perfectly competitive market, the rational profit maximizing competitor has no choice as to price; it cannot sell for more than its competitors charge, and it has no reason to sell for less. Market power is the ability to act in less than this perfectly competitive manner.

14. Monopoly power has been defined as the power to fix prices, to exclude competitors, or to control the market in the relevant geographic area in question.

15. See, L. Sullivan, Handbook of the Law of Antitrust Section 69 (1977).

16. 435 U.S. 679 (1978).

17. Vendervette v. Put & Call Brokers Assn., 344 F. Supp. 118, 136 (S.D.N.Y. 1972); see Proger, supra, at pp. 6-7; United States v. Socony Vacuum Oil Co., 310 U.S. 150, 223 (1940) ("a combination formed for the purpose and with the effect of raising, depressing, fixing, pegging, or stabilizing the price of a commodity in interstate or foreign commerce . . ."). An agreement on credit terms has also been held to be illegal price-fixing. (See Catalano, Inc. v. Target Sales Inc., 446 U.S. 643 (1980). As the doctrine stands, it is not only illegal per se for competitors to horizontally agree on price, it is also illegal per se for a wholesaler to agree with a retailer on the price at which the retailer will resell the goods. Dr. Miles Medical Co. v. John D. Park & Sons Co., 220 U.S. 373 (1911) (vertical agreement fixing minimum retail prices).

    The U.S. Supreme Court has recently held that arrangements in the health care field that sufficiently resemble classical price-fixing are subject to the same rules of per se illegality that are applied to any other industry, notwithstanding arguments to the contrary based on the unique characteristics of the health care marketplace. Arizona v. Maricopa County Medical Society, 102 S.Ct. 2466 (1982). "We are equally unpersuaded by the argument that we should not apply the per se rule in this case because the judiciary has little antitrust experience in the health care industry." Id. at 2476.

18. See, e.g., Fashion Originator's Guild v. Federal Trade Commission,312 U.S. 457 (1941). There is some current confusion over the nature and scope of the prohibition on concerted refusals to deal because they include agreements that are not perniciously anticompetitive or without redeeming competitive virtue. The Supreme Court has said that such arrangements are per se violations of the antitrust laws. However, the lower courts reflect the doubts over the competitive impact of various types of concerted refusals to deal and have given rule of reason analysis to several classes of refusal to deal arrangements.

19. United States v. Topco Associates, 405 U.S. 596 (1972).

20. See, e.g., Addyston Pipe & Steel Co. v. United States, 175 U.S. 211 (1899) Timken Roller Bearing Co. v. United States, 341 U.S. 893 (1951).

21. In American Column & Lumber Co. v. United States, 257 U.S. 377 (1921) the Supreme Court established that the Sherman Act may prohibit exchanges of information among competitors when those exchanges lead to anticompetitive behavior.

22. Dr. Miles Medical Co. v. John D. Park & Sons, 220 U.S. 373 (1971).

23. See, e.g., International Salt Co. v. United States, 332 U.S. 392, 397-98 (1947) (seller attempted to justify its practice of tying

the purchase of its salt to the leasing of its patented canning machine, claiming that the machines would function properly only if a certain type of salt were used. The court refused to apply the goodwill defense because the less restrictive alternative of specifying the type of salt to be used was available); United States v. Jerrold Electronics Corp., 365 U.S. 567 (1961) (tie-in of servicing to product allowed to assure adequate performance of the highly technical new product).

24. Compare, Standard Oil Co. of California v. United States, 337 U.S. 293 (1949) (quantitative test) with Tampa Electric Co. v. Nashville Coal Co., 365 U.S. 320 (1961) (qualitative test). Important factors in these cases include:

    (1) the business reason for the contract;

    (2) whether a business is just getting started and needs to have the assurance that its distributors will sell only its products;

    (3) whether the buyer wants the exclusive contract or whether it is imposed by the seller;

    (4) the length of time that the contract is to run;

    (5) the amount of the sale; and finally

    (6) the size of the market share foreclosed.

25. 15 U.S.C. Section 2 (1976).

26. See, United States v. Grinnel Corp., 384 U.S. 563, 570-571 (1966).

27. See, United States v. E.I. DuPont de Nemours & Co., 351 U.S. 377, 392 (1956); American Tobacco Co. v. United States, 328 US. 781, 811 (1946); Standard Oil Co. v. United States, 221 U.S, 27-28 (1911). The monopoly power of a potential Sherman 2 violator is determined by looking at the percentage of the market occupied by the defendant in the relevant market. The relevant market, the denominator of the market share fraction, is determined by analyzing both the product and geographic markets.

28. See, United States v. E. I. DuPont de Nemours & Co., 351 U.S. 377, 393-400 (1956). A relevant product market is composed of "all products that have reasonable interchangeability for the purposes for which they are produced: price, use and quality considered." While the reasonable interchangeability test is still the starting point for product market determinations, post-DuPont decisions under Section 7 of the Clayton Act have accepted what is termed "submarket analysis" as the proper method of determining a relevant product market. Submarket analysis focuses on commercial realities (e.g., buyer preferences,

physical differences, and established trade practices) to determine if there are any cognizable submarkets within the broader market of all reasonably interchangeable products. This method usually results in narrow relevant product markets. The method used is often crucial in Sherman 2 cases, since the narrower the relevant product market defined, the higher defendants share of that market becomes, and the more likely that a finding of monopoly power will be made. See United States v. Grinnell Corp., 384 U.S. 563 (1966).

30. Monopolies have been found by the courts where eighty to ninety percent is under defendant control. See, e.g., United States v. Grinnell Corp., 384 U.S. 563, 571 (1966 (87%): International Boxing Club, Inc., v. United States American Tobacco Co., 221 U.S. 106, 164-663 (1911) (over 90%); United States v. Aluminum Co. of America, 148 F.2d 416, 424 (2d Cir. 1945) (90% is enough, 60% likely not enough, 33% not enough. The courts have, however, set out other guidelines as well. For instance, the following have been suggested: 1) 75% is enough, 25% is not enough. United States v. E. I. DuPont de Nemours & Co., 351 U.S. 377 (1956); 2) 90% is enough, 60% is not likely to be enough; 33% is not enough. United States v. Aluminum Co. of America, 148 F.2d 416, 424 (2d Cir. 1945). 3) less than 50% is not enough. Cliff Stoves Inc. v. Kroger, Inc., 417 F.2d 203, 207 n. 2, 5th Cir. 1969.

30. See United States v. Aluminum Co. of America, 148 F.2d (2d Cir 1945); United States v. United States Machine Corp., 110 F. Supp 295 (D. Mass. 1953), aff'd per curiam, 347 U.S. 501 (1954).

31. Id. at 396. Some courts do not require a showing of dangerous probability of success. See, Lessing v. Tidewater Oil Co., 327 F.2d 459 (9th Cir.) cert. denied, 377 U.S. 933 (1964).

32. 15 U.S.C. Section 45 (1976).

33. Federal Trade Commission v. Brown Shoe Co., 384 U.S. 316 (1966).

34. Federal Trade Commission v. Sperry and Hutchinson Co., 405 U.S. 233 (1972).

35. 15 U.S.C. Section 44 (1976).

36. It is a complex and highly technical statute that is not discussed in this paper.

37. See, Goldfarb v. Virginia State Bar, 421 U.S. 773, n. 15 (1975). Accord; National Society of Professional Engineers v. United States, 435 U.S. 679 (1978) Arizona v. Maricopa County Medical Society, 102 S. Ct. 2466 (1982). In Goldfarb v. Virginia State Bar, the Supreme Court rejected a claim that price-fixing by lawyers should be exempted from the antitrust laws because the

price-fixing was undertaken by a professional group. 421 U.S. 773 (1975).

38. See, Goldfarb v. Virginia State Bar, 421 U.S. 773, n. 15 (1975). 421 U.S. 773, 788 n. 17.

39. See, United States v. Oregon State Medical Society, 343 U.S. 326, 336 (1952); Goldfarb v. Virginia State Bar, 421 U.S. 733, 788 n. 17 (1975); Bates v. State Bar of Arizona, 433 U.S. 350, 368-70 (1977); National Society of Professional Engineers v. United States, 435 U.S. 679, 696 (1978).

40. See, Arizona v. Maricopa County Medical Soc'y, 102 S.Ct. 2466 (1982), again noting the possibility of special treatment for professional services but holding maximum fee scheduling by physicians' organizations per se illegal.

41. See, McLain v. Real Estate Board of New Orleans, Inc., 444 U.S. 232 (1980); Hospital Building Co. v. Trustees of Rex Hospital, 425 U.S. 738 (1976) Note also that the interstate commerce defense does not apply to actions brought under state antitrust laws.

42. See, Parker v. Brown, 317 U.S. 341 (1943).

43. See, California Retail Liquor Dealers Association v. Midcal Aluminum, Inc., 445 U.S. 97 (1980) (holding that the state action exemption will not apply unless the challenged restraint is a clearly articulated and affirmatively expressed state policy and that policy is actively supervised by the state itself). Id. at 105.

44. United States v. Topco Associates, 405 U.S. 596 (1972).

45. Proger, supra, p. 11:

> "Assume that there are two competing hospitals in one city and they get together and they say, well, we don't have enough obstetrics to justify two hospitals having obstetrics so you, hospital A, will take care of the obstetrics. Hospital B will take care of . . . all psychiatric care and they divide up the market that way. Or take the other situation, a geographic division of the market. Hospital A is on the east end of the city and hospital B is on the west end, and they say, o.k., hospital A will take all patients that live and reside on the east end of the city and B all patients that reside on the west end. So we will never compete for the same patients.

46. From Evans et al., The Health Technology Assessment of Heart Transplantation, 1983; Problems and Prospects unpublished manuscript, Battelle HARC, 1983).

47. Moore, Letter to the Editor: MGH Trustees Say No to Heart Transplants. 303 New England Journal of Medicine 999 (1980):

> In a nation this size, there should be four or five centers where heart and liver transplantation can be performed competently. . . several hospitals in Boston should share this responsibility working together without competition.

48. Moore, How Much Cardiac Transplantation -- And Where? 1 Heart Transplantation 254 (1982).
49. Id.

50. Copeland and Stinson, Human Heart Transplantation, 4 Current Problems in Cardiology 4 (1979).

51. Havighurst, Competition in Health Services, 34 Vanderbilt Law Review 1117, 1153 (1981).
52. Among the specialities currently offered under exclusive staffing arrangements are: Radiology see, e.g., Harron v. United Hospital Center, Inc., 522 F.2d 1133 (4th Cir. 1975); Malini v. Singleton & Assoc., 516 F. Supp. 440 (S.D. Tex. 1981); Centeno v. Roseville Community Hospital, 167 Cal. Rptr. 183 (Ct. App. 1979); Letsch v. Northern San Diego County Hospital District, 55 Cal. Rptr. 118 (Ct. App. 1966); Blank v. Palo Alto-Stanford Hospital Center, 44 Cal. Rptr. 472 (Ct. App. 1965); Hayden v. Stanford University Hospital, No. 32039 (Cal. Super. Ct., July 8, 1979); Radiology Professional Corp. v. Trinidad Area Health Association, Inc., 577 P.2d 748 (Colo. 1978); Rush v. City of St. Petersburg, 205 S.2d 11 (Fla. Dist. Ct. App. 1967); Rumple v. The Bloomington Hospital, 1981-2 Trade Cas. (CCH) Paragraph 64, 156 (Ind. Ct. App. 1981); The Anne Arundel General Hospital, Inc. v. O'Brien, 432 A.2d 483 (Md. 4 Spec. App. 1981); Bennell v. City of Virginia, 104 N.W.2d 633 (Minn. 1960); Nuclear medicine, see e.g., Datillo v. Tucson General Hospital, 533 P.2d 700 (Ariz. Ct. App. 1975). Renal dialysis, see e.g., Denver v. Santa Barbara Community Dialysis Center, 1981-1 Trade Cas. (CCH) Paragraph 63,946 (C.D. Cal. 1981); Lewin v. St. Joseph Hospital of Orange County, 146 Cal. Rptr. 892 (1978); Pathology, see e.g., Crane v. Intermountain Health Care, Inc., 637 F.2d 715 (10th Cir. 1980); Datillo v. Tucson General Hospital, 533 P.2d 700 (Ariz. Ct. App. 1975). Anesthesiology, see e.g., Hyde v. Jefferson Parish Hospital District No. 2, 686 F.2d 286, cert. granted ___ U.S.L.W. ___ (1983); Nelson v. Galesburg Cottage Hospital, No. 80-1233 (C.D. Ill. 1981); Capili v. Shott, 487 F. Supp. 710 (S.D.W. Va. 1978), aff'd, 620 F.2d 438 (4th Cir. 1980); Douglas v. Hospital of St. Raphael, 371 A.2d 396 (Conn. 1976); Margolin v. Morton F. Plant Hospital Association, Inc., 342 S.2d 1090

(Fla. Dist. Ct. App. 1977); Emergency rooms, see e.g., Smith v. Northern Michigan Hospital, Inc., 518 F. Supp. 644 (W.D. Mich. 1981); Khan v. Suburban Community Hospital, 340 N.E.2d 398 (Ohio 1976); and major surgery see e.g., Jeanes v. Burke, 226 S.W.2d 908 (Tex. Civ. App. 1950).

53. Robinson v. Magovern, 521 F. Supp. 842 (W.D. Pa. 1981); aff'd mem., 668 F.2d 824 (3rd Cir. 1982,) cert. denied, ___U.S.___, 103 S.Ct. 302 (1983); Sokol v. University Hospital, Inc., 402 F. Supp. 1029 (D. Mass. 1975); Geiger v. St. Mary's Hospital and Medical Center, No. 34595 (Cal. Ct. App., February 10, 1975); O'Connell v. Mt. Zion Hospital, No. 683-063 (Cal. Super. Ct., November 26, 1974); Molesv. White, 336 S.2d 427 (Fla. Dist. Ct. App. 1976).

54. Cardiomedical Associates Ltd. v. Croser Chester Medical Center, 536 F. Supp. 1065 (1982); Powsner v. St. Joseph Mercy Hospital of Detroit, No. 77-5279 (Mich. Cir. Ct. December 1, 1977); Adler v. Montefiore Hospital Association of Western Pennsylvania, 311 A.2d 634 (Pa. 1973), cert. denied, 414 U.S. 1131 (1974); (Cardiac catheterization).

55. See e.g., Robinson v. Magovern, 521 F. Supp. 842 (W.D. Pa. 1981); Smith v. Northern Michigan Hospital Association, Inc., 581 F. Supp. 644 *see new cite (W.D. Mich. 1981); Powsner v. St. Joseph Mercy Hospital of Detroit, No. 77-5279 (Mich. Cir. Ct. Dec. 1, 1977).

56. Foster, Exclusive Arrangements Between Hospitals and Physicians Antitrust Next Frontier in Health? 26 St. Louis University Law Journal 535, 539 (1982).

57. Copeland and Stinson, Human Heart Transplantation, 4 Current Problems in Cardiology 4-51 (1979), cited in Evans, Overcast, Garrison et al., Problems and Prospects in Heart Transplantation 1983, Battelle HARC 1982.

58. Havighurst, Antitrust Enforcement in the Medical Services Industry, 58 Milbank Memorial Fund Quarterly 89-124, 106 (1980). In Saint Paul Fire & Marine Insurance Co. v. Barry, the Court limited the McCarran-Ferguson exemption by broadening the meaning of boycott, which previously had been interpreted as covering only boycotts directed against insurance companies or their agents, to include disputes between insureds and insurers. In Group Insurance Life and Health Insurance Co. v. Royal Drug Co., the Supreme Court further narrowed the business of insurance exemption to (1) insurance contracts between insurers and insureds, (2) risk spreading activities, and (3) practices limited to entities within the insurance industry. In Union Labor Life Insurance Co. v. Pireno, 102 S.Ct. 3002, the Court again interpreted the scope of the business of insurance exemption narrowly. It held that the activities of peer review

committees, which review the necessity of services provided and the reasonableness of fees charged, do not constitute the business of insurance under the three criteria identified in Royal Drug.

Pireno involved a peer review committee established by the New York State Chiropractic Association to aid insurers in evaluating claims for chiropractic treatment. One insurance company submitted for review claims made by Dr. Pireno. The peer review committee decided that some of the services provided by Dr. Pireno were unnecessary and that some of his fees were unreasonably high. As a result, the insurance company refused to pay the claims. Dr. Pireno sued both the insurance company and the state Association of Chiropractors that had set up the committee, alleging an illegal restraint of trade and a conspiracy to fix prices. The trial court held that the practice fell within the business of insurance exemption, 650 F.2d 387, 388 (2d. Cir. 1981), and the second circuit reversed. Id. at 387.
The peer review process reviewed in Pireno fell outside the exemption since it: (1) did not involve the underwriting or the spreading of risk, (2) did not involve agreements between the insurer and insured, and (3) was not limited to entities within the insurance industry.

59. See, Havighurst, Professional Restraints on Innovation in Health Care Financing, 1978 Duke Law Journal 303, 304-5 (1978).

60. Havighurst, Competition in Health Services, 34 Vanderbilt Law Review 1117, 1130(1981) (cited hereafter as Competition).

61. The following discussion relies heavily on Havighurst, Competition, pp. 1127-29.

62. See C. Havighurst, Competition.

63. Havighurst, Professional Restraints on Innovation in Health Care Financing, 1978 Duke Law Journal 303, 306-07 (1978).

64. An extensive discussion of these practices and their antitrust implications is beyond the scope of this section. They are discussed in Havighurst, Professional Restraints.

65. See Havighurst, Professional Restraints, p. 354, and Heitler, Antitrust, Restraint of Trade, and Unfair Business Practices, 3 Journal of Legal Medicine 443, 451 (1982)) suggesting that a per se rule should be applied.

66. In a recent FTC opinion, the Michigan State Medical Society was held to have violated FTCA 5 by conspiring with its members to influence insurers' reimbursement policies by seeking to negotiate collective agreements with insurers, by agreeing to use coercive measures like proxy solicitation for "departicipation,"

by concerted refusals to deal, and by actually making coercive threats to insurers. (In re Michigan State Medical Society, 44 A.T.R. 426, 2/24/83.) And in In re Indiana Federation of Dentists, at 44 A.T.R. 398 (2/24/83), the FTC found that a dentists' organization had violated FTCA 5 by encouraging its members to refuse to provide X-rays to dental insurers for use in a method of benefit determination that was adopted as a cost containment measure.

67. Concerted, not unilateral, action is subject to the strictures of the antitrust laws. It is necessary to prove the existence of a "contract, combination, or . . . conspiracy" to refuse to deal. Sherman Act Sec. 1, 15 U.S.C. Sec. 1 (1976). While an explicit call to boycott an innovative provider or insurer easily satisfies this agreement requirement, it is unusual to find actual documentation of an agreement or explicit invitation to boycott. However, a conspiracy can often be inferred from collective actions likely to produce uniform behavior that amounts to a boycott. Thus, as Havighurst has pointed out, circulation of certain kinds of information likely to induce parallel action has been held to warrant a finding of a concerted refusal to deal. Havighurst, Professional Restraints, at 345, citing Eastern States Retail Lumber Association v. United States, 234 U.S. 600 (1914). But an inference of conspiracy would not be permissible if based solely on information circulated that was otherwise difficult to obtain and had value to the recipients above and beyond its utility as a signal for collective action. Id., citing Cement Manufacturers' Protective Association v. United States, 268 U.S. 588, 604 (1925). Proof of widespread individual refusals to deal is not adequate to establish the requisite conspiracy, because unilateral refusals to deal are permitted. United States v. Colgate & Co., 250 U.S. 300, 307 (1919). An inference of conspiracy from conscious parallelism is not compelled where the alleged conspirators may have had independent reasons for doing what they did. Theatre Enterprises, Inc. v. Paramount Film Distribution Corp., 346 U.S. 537 (1954).

68. 102 S.Ct. 2466 (1982). At issue were the fee schedules adopted by the foundations for medical care established by two county medical societies. Under the foundation membership agreements, physicians agreed among themselves to adhere to a schedule of maximum fees established by majority vote. The Supreme Court held that the foundation membership agreements constituted horizontal price-fixing and, therefore, were illegal per se.

69. See Fried, The Impact of Recent Antitrust Case Law on Health Care Professionals, 10 Law, Medicine and Health Care, 254 (1982).

70. For relatively brief and opposing views of the implications of Maricopa, see Cohen and Tiano, The Aftermath of Maricopa, 10 Law, Medicine and Health Care 248 (1982).

71. 15 U.S.C. Sections 1011-1015 (1976).

72. 15 U.S.C. Section 1013(b) (1976).

73. BCBS contracts with the insured subscriber (subscriber contracts) to provide health care services, and contracts with the preferred providers who agree to perform the health care services provided for in the contract (participating provider agreements- PPAs).

74. See, e.g., Medical Arts Pharmacy of Stamford, Inc. v. Blue Cross and Blue Shield of Conn. Inc., 518 F. Supp 1100 (D. Conn. 1981), aff'd., 675 F.2d 502 (2d Cir. 1982); Sausalito Pharmacy Inc. v. Blue Shield of Cal., 1981-1 Trade Cas. (CCH), paragraph 63, 885 (N.D. Cal. 1981), aff'd per curiam, 677 F.2d 47 (9th Cir. 1982); Glen Eden Hospital, Inc. v. Blue Cross and Blue Shield of Michigan, 555 F. Supp 337 (1983).

75. 518 F. Supp 1100 (D. Conn. 1981), aff'd, 657 F.2d 502 (2d Cir. 1982). The court rejected the plaintiff's contention that the agreements constituted horizontal price fixing or maximum resale price maintenance by noting that the per se rule applies to agreements to fix the price to be charged in transactions with third parties, not between the contracting parties themselves. 518 F. Supp at 1107, citing Sitkin Smelting and Refining Co. v. FMC Corp., 575 F.2d 440, 446 (3rd Cir.), cert. denied, 439 U.S. 866 (1978).

76. Sausalito Pharmacy, Inc. v. Blue Shield of Cal., 1981-1 Trade Cas. (CCH) paragraph 63,885 (N.D. Cal. 1981), aff'd per curiam, 677 F.2d 47 (1982).

77. 677 F.2d 47, 48 (1982).

78. The Supreme Court's characterization in Royal Drug . . . of virtually identical arrangements as "arrangements for the purchases of goods and services" was not mere dicta but was essential to the outcome of the case, and therefore dictates the view which this Court must adopt. We therefore hold that the pharmacy agreements at issue here constitute agreements between the buyers and sellers of goods."

79. Id. at 75,609-10.

80. 555 F. Supp 337 (E.D. Mich. 1983).

81. Count 1 of the complaint alleged that BCBS acted in concert with other hospitals, in competitors of Glen Eden, to use coercion and threats of boycott or refusals to deal to force Glen Eden to accept BCBS's non-competitive reimbursement system. Glen Eden claimed that Blue Cross unlawfully refused to deal with it by terminating its preexisting non-participating psychiatric

hospital (NPPH) contract under which it would be reimbursed for its reasonable and customary charges not exceeding the average per diem payment to participating hospitals, and refusing all reimbursement unless Glen Eden accepted the participating hospital agreement. The agreement provided that either party could terminate on 30 days notice. In the letter of termination, Blue Cross stated that it was terminating the NPPH contract because state law had been amended 6 years previously that would allow Glen Eden to become a participating hospital. Glen Eden also alleged that an unlawful refusal to deal was manifested by defendant's refusal to reimburse plaintiff on an experimental basis or to permit it to have access to defendant's computer. Glen Eden also contended that BCBS's refusal to approve a proposed new facility in Michigan also involved an unlawful refusal to deal. Id. at 340.

Count II alleged that BCBS attempted to, conspired to, and did in fact, monopolize the health care industry in Michigan in violation of Section 2 of the Sherman Act, and that it abused its monopoly powers by engaging in refusals to deal, boycotts, by fixing a non-competitive reimbursement scheme, and preventing expansion of competing hospitals.

Count III alleged a violation of the Michigan antitrust law, and Count IV alleged a breach of the NPPH contract.

82. No provider control of BCBS's reimbursement policy existed, unlike the situation in both Maricopa and Virginia Academy of Clinical Psychologists v. Blue Cross Blue Shield. 624 F.2d 476 (4th Cir. 1980), cert. denied, 450 U.S. 916 (1981). (Blue Shield plan found to be a combination of physicians, and controlled by physicians). The court also rejected a resale price fixing claim because no coercive activity or collaboration with others was established.

83. Id. at 344. The court also rejected the group boycott claim because Blue Cross's insistence upon certain terms in its contract with providers did not amount to a boycott.

84. The court also made no determination of defendants' monopoly power in the relevant market. First, the court noted that because BCBS offered to deal with Glen Eden on the same terms as all other participating hospitals, there was no monopolizing conduct. Further, the court noted that a monopolist may unilaterally refuse to deal as long as the refusal does not extend or maintain the monopolist's monopoly power. And the court noted that BCBS was not an actual or potential competitor of Glen Eden, so its failure to deal with them did not affect its market position in any way.

85. Des Granges Psychiatric Center, PC v. Blue Cross and Blue Shield of Michigan, 44 A.T.R. 808 (Mich. Ct. App. 1983).

86. 624 F.2d 476 (4th Cir. 1980), cert. denied, 450 U.S. 916 (1981).

87. See Evans, Economic and Social Costs of Heart Transplantation, 1 Heart Transplantation 243 (1982). It is not clear how much of the difference in costs reported by transplant centers is due to different methods of assessing costs.

88. Borsody and Tiano, Peer Review and the Antitrust Laws: An Analysis and a Proposal, 26 St. Louis University Law Review 511, 512 (1982).

89. Union Labor Life Insurance Co. v. Pireno, 102 S.Ct. 3002 (1982). Pireno however, did not address the merits of the underlying Sherman Act claims. Id. at 3007.

90. Prottas, Obtaining Replacements: The Organizational Framework of Organ Procurement, unpublished manuscript, August, 1982, p. 11.

91. Id. In addition, all are funded by the ESRD program. The government pays 100% of kidney acquisition costs. DPAs are therefore solely dependent on the government for financing, but they are not governmental agencies in a legal sense.

92. See Goldfarb v. Virginia State Bar, 412 U.S. 773 (1975).

93. 15 U.S.C. Section 44.

94. American Medical Association v. Federal Trade Commission, 94 FTC 701-983 (1979), aff'd with slight modifications to the cease and desist order, 639 F.2d 443 (2d Cir. 1980), aff'd by an equally divided court without written opinion, 50 U.S.L.W. 4313 (U.S. March 23, 1982).

95. See also the Non Profit Institutions Act, 15 U.S.C. Section 13(c), which exempts from the Robinson-Patman Act purchases by non-profit institutions of supplies for the institutions own use. See Abbott Laboratories v. Portland Retail Druggist Association, 425 U.S. 1 (1976).

96. Prottas, Organizational Effectiveness in Organ Procurement: A Study of Independent Organ Procurement Agencies, unpublished manuscript, April, 1982, p. 76. Prottas estimated that more than 40% of kidneys are transplanted to someplace other than the location where they were procured. There is a computer registry system that lists the potential kidney recipients of all transplant facilities east of the Rocky Mountains. The OPA with the extra organ simply enters the tissue test results of the kidney and asks the computer for matches. The computer then prints all recipients with antigen match, and the agency on whose list the recipient appears.

97. Id. at 82. Each agency quickly develops a reputation that is difficult--if not impossible to alter rapidly. Agencies with poor reputations will be avoided. Organs offered by them are less likely to be accepted, and the impact extends to offering their kidneys. . . Therefore, a transplant team where associated organ procurement agency has a poor reputation, will suffer, perhaps quite unfairly. . . Agencies that develop a reputation for being slow to respond to offers to export a kidney may also become pariahs.

98. 70 F.T.C. 728 (1966), rev'd on other grounds, 405 F.2d 1011 (8th Cir. 1969).

99. 405 F.2d at 1019. On appeal, the lack of demonstrated commercial purpose was held effectively to deprive the FTC of jurisdiction over the non-profit corporations involved since they had not been shown to be organized for the profit of their members as required by 15 U.S.C. Section 44.

100. Id. at 943-44.

101. See, Note, The Sale of Human Body Parts, 72 Michigan Law Review 1182 (1974); Note, Retailing Human Organs Under the Uniform Commercial Code, 16 John Marshall Law Review 393 (1983).

102. Radiant Burners, Inc. v. Peoples Gas Light & Coke Co., 364 U.S. 646 (1961); Kloss, Inc. v. Broadway Hale Stores, Inc., 359 U.S. 207 (1959); Associated Press v. United States, 326 U.S. 1 (1945).

103. Fashion Originators Guild of America, Inc. v. Federal Trade Commission, 312 U.S. 457, 467-68.

104. 421 U.S. 778-79, n.17.

105. 435 U.S. 679 (1978).

106. Id. at 692.

107. Id. at 696 (citing with approval Goldfarb v. Virginia State Bar, 421 U.S. 773, 778-89 n. 17 (1975). "Ethical norms may serve to regulate and promote this competition and thus fall within the rule of reason."

108. 102 S.Ct. 2466 (1982). Maricopa involved an alleged price-fixing agreement among physicians. The defendants were the Maricopa and Pima County medical societies, and the foundations created by each. At issue were the fee schedules adopted by the two foundations. The State of Arizona, plaintiff in the case, charged that the defendants placed maximum limits on the fees that physicians could charge subscribers of several specified health insurance plans and

that these schedules amounted to illegal maximum price-fixing, a per se violation of the antitrust laws. The state thus asked the court to declare the agreements illegal without a trial, thereby denying the defendants the opportunity to demonstrate the procompetitive aspects of the practice under the rule of reason.

The federal district court held, and the court of appeals for the ninth circuit affirmed, that fee arrangements were not per se illegal and that the state would have to prove the unreasonableness of the agreements at trial. Arizona v. Maricopa County Medical Society, 643 F.2d 553, 554 (9th Cir., 1981) overruled 102 S.Ct. 2466 (1982). On appeal, the U.S. Supreme Court ruled 4 to 3 (Justices Blackmun and O'Connor did not participate in consideration of the case) that, notwithstanding the possibility that the practice could be viewed as procompetitive after detailed analysis, the agreement sufficiently resembled classical price-fixing so as to require the application of the per se rule.

109. See, e.g., Kartell v. Blue Shield of Massachusetts, 542 F. Supp. 782 (D. Mass. 1982). But see Hyde v. Jefferson Parish Hospital Dist. No. 2, 686 F.2d 286 (5th Cir. 1982), cert. granted, ____ U.S.L.W. ____ (1983). Exclusive contract between hospitals and anesthesiology group held to be an illegal per se tying arrangement.

110. 44 A.T.R. 426 (1982).

111. 44 A.T.R. 398 (1982).

112. The Commissioners refusal covered 3 points. First, the type of restrictions challenged have not been the subject of frequent prior antitrust analysis. Second, the FTC found that the respondents' activities were not wholly motivated by an anticompetitive motive and thus were not appropriate for per se analysis. Third, even though the restraints could be viewed as a group boycott -- this particular boycott was not aimed principally at excluding competitors, which the Commissioners felt made per se analysis less appropriate.

113. 44 A.T.R. 426, 438.

114. Id, at 446-48.

115. United States v. Oregon State Medical Society, 343 U.S. 326 (1952).

116. 513 F.2d at 686. See, United States v. Oregon State Medical Society, 343 U.S. 326, 337-39, (1952); Wolf v. Jane Phillips Episcopal-Memorial Medical Center, 513 F.2d 684, 686. (10th Cir. 1975); Riggall v. Washington County Medical Society, 249 F.2d 266, 268 (8th Cir. 1957), cert. denied, 355 U.S. 954

(1958); Spears Free Clinic and Hospital for Poor Children v. Cleere, 197 F.2d 125, 126 (10th Cir. 1952); Elizabeth Hospital Inc., v. Richardson, 167 F. Supp 155, 160 (W.D. Ark. 1958), aff'd, 269 F.2d 167 (8th Cir.), cert. denied, 361 U.S. 884 (1959). But see Doctors Inc. v. Blue Cross, 490 F.2d 48 (3rd Cir. 1973).

117. See, e.g., McLain v. Real Estate Board, 444 U.S. 232 (1980); Burke v. Ford, 389 U.S. 320, 322 (1967); U.S. v. Women's Sportswear Manufacturers' Association, 336 U.S. 460, 464 (1949).

118. See, Hospital Building Co. v. Trustees of the Rex Hospital, 425 U.S. 738 (1976).

119. Notably, McLain v. Real Estate Board of New Orelans, Inc. 444 U.S. 232 (1980). and Hospital Building Co. v. Trustees of Rex Hospital (425 U.S. 738 (196)).

120. See Crane v. Intermountain Health Care, Inc., 637 F.2d 715 (10th Cir. 1981).

121. Addyston Pipe and Steel Co. v. United States, 175 U.S. 211 (1899); Northern Securities Co. v. United States, 193 U.S. 197 (1904); Swift & Co. v. United States, 196 U.S. 375 (1905). The flow of commerce test arose as an attempt to avoid the strictures of an early decision that used the concept of commerce in a narrow sense. In United States v. E.G. Knight Co., 156 U.S. 1 (1895), the Court held that mere manufacturing was not "commerce" and thus a monopoly of sugar manufacture was not covered by the Sherman act. Such restrictive doctrines have since been put to rest.

122. The affecting commerce test was adopted in the case of Manderville Island Farms v. American Crystal Sugar Co., 334 U.S. 299 (1948). The Court held that agreements to fix the price paid to sugar beet growers in California violated the Sherman Act even though the beets-to-sugar manufacturing process occurred before any shipment into interstate markets had occurred. Pointing to the relationship of the price of beets to the price of sugar, the Court held that the consequences of the agreement were projected substantially into the interstate distribution of the sugar: "the vital thing is the effect on commerce, not the precise point at which the restraint occurs." Id. at 238.

123. United States v. Women's Sportswear Manufacturers's Association, 336 U.S. 460, 464 (1949). In Hospital Building Co. v. Trustees of Rex Hospital, a small proprietary hospital in North Carolina alleged that a large voluntary facility and health planning agency Attempted to block its expansion, in violation of the Sherman Act. The lower courts found an insufficient connection to interstate commerce and dismissed

the case. The Supreme Court held that if the allegations were true, the hospital's claim that it purchased 80% of its supplies in interstate commerce, treated a substantial number of out-of-state patients, received a large portion of its revenues from out-of-state insurance carriers, had a management contract with an out-of-state corporation, and planned to finance its expansion through out-of-state lenders, satisfied the Court's requirement of sufficient contact with interstate commerce.

124. 444 U.S. at 246. The Court found it sufficient that "whatever stimulates or retards the volume of residential sales, or has an impact on the purchase price, affects the demands for financing and title insurance, those two commercial activities that on this record are shown to have occurred in interstate commerce."

125. The Court, however, added confusion by stating later in the opinion, "To establish federal jurisdiction in this case, there remains only the requirement that the respondents' activities which allegedly have been infected by the price fixing conspiracy be shown . . . to have a not insubstantial effect on interstate commerce involved." 444 U.S. 232, 246 (emphasis added).

126. 634 F.2d 715 (10th Cir. 1981). In Crane, a pathologist filed a Sherman 1 suit against the corporate owner and administrator of the Cottonwood Hospital, alleging a conspiracy that required, among other things, that all pathology specimens of Cottonwood patients be evaluated by Cottonwood's pathology laboratory to the exclusion of the doctors' laboratory. 637 F.2d at 722-24.

127. __ F.2d__, 52 U.S.L.W. 1035 (3d. Cir. 1983). The Pennsylvania district court dismissed a physician's complaint against a hospital that had denied him the opportunity to perform certain medical procedures, saying that the plaintiff had failed to allege a legally relevant channel of interstate commerce, a substantial effect on interstate commerce, and any nexus between the acts complained of and interstate commerce. 536 F. Supp. 1065 (1982), rev'd __ F. 2d __, U.S.L.W. 1035 (3rd Cir. 1983). On appeal, however, the Court of Appeals noted that the district court's theory "reflects a misunderstanding of the role the commerce clause plays in the Sherman Act. Anticompetitive conduct may occur locally as well as in interstate commerce. . .
. . .There is no reason why an enterprise engaged in nationwide anticompetitive conduct should not be subject to suit by a local victim simply because the defendant's conduct, as regards that particular plaintiff, does not affect interstate commerce."

128. Hahn v. Oregon Physicians Service, 42 A.T.R.R. 765 (9th Cir. 1982).

129. 317 U.S. 341, 368 (1943). The Parker decision offers little guidance on the degree of state involvement necessary for a finding of state action. While later cases have clarified the requirements to some extent, these decisions are not entirely consistent, and leave a number of questions unanswered. A number of articles have discussed the Parker doctrine. See, e.g., Handler, "The Current Attack on the Parker v. Brown State Action Doctrine," 76 Columbia Law Review 1 (1976). Later cases may have narrowed the doctrine. See, Cantor v. Detroit Edison Co., 428 U.S. 579 (1976); Goldfarb v. Virginia State Bar 421 U.S. 773 (1975).

130. 445 U.S. 97 (1980).

131. Thompson and Scott, Antitrust Considerations and Defenses in Reorganizing for Multi-institutional Activities, 26 St. Louis University Law Journal 465, 497-98 (1982), citing Goldfarb v. Virginia State Bar, 421 U.S. 773, 790-91 (1975), and Cantor v. Detroit Edison Co., 428 U.S. 579, 591 (1976). Phillip Areeda, in contrast, does not believe that compulsion is a critical element:

> "although the absence of compulsion was emphasized as grounds for denying Parker immunity in Goldfarb and Cantor, compulsion does not seem critical to immunity where the challenged behavior is an integral part of a valid state regulatory scheme. For example, a state utility regulation does not compel a utility to file any particular rate. Nevertheless, control through the antitrust laws of utility rates activity supervised by a state regulatory agency would seem inconsistent with a valid regulatory scheme and should therefore be held immune from the antitrust laws." P. Areeda, Antitrust Analysis (3d ed. 1981) Sec. 181(c) (hereinafter referred to as "Areeda").

Compulsion may indicate both a state purpose to substitute regulation for competition and active state supervision.

132. Goldfarb v. Virginia State Bar 421 U.S. 773 (1975).

133. 433 U.S. 350 (1977).

134. Cantor v. Detroit Edison Co., 428 U.S. 579 (1976).

135. Areeda, Section 181(c).

136. But see New Motor Vehicle Board v. Orrin W. Fox Co., 439 U.S. 96 (1978) (individual hearings by the state franchising board is sufficient to meet the supervision prong).

137. National Gerimedical Hospital and Gerontology Center v. Blue Cross of Kansas City, 101 S.Ct. 2415 (1981); Gordon v. New York Stock Exchange, 442 U.S. 659, 682-84 (1975); Silver v. New York Stock Exchange, 373 U.S. 341, 357 (1963).

138. (Gordon v. New York Stock Exchange, 422 U.S. 659, 682 (1975)).

139. See United States v. National Association of Security Dealers, Inc., 422 U.S. 694 (1975).

140. 101 S.Ct. 2415 (1981). National Gerimedical, a private, acute care community hospital, sought to enter into a participating hospital contract with Blue Cross-a move that would allow the hospital to receive direct reimbursement of 100% of the cost of covered services. Hospitals without participating hospital status cannot receive direct payment and Blue Cross pays only 80% of the cost. Blue Cross denied National Gerimedical participating hospital status because of a Blue Cross policy barring participation by any new hospital that could not demonstrate that it was meeting "a clearly evident need for health care services in its defined service area." In making its status determination , Blue Cross relied on the fact that the hospital had failed to gain approval for construction by the local Health Systems Agency (HSA). The hospital said it had not sought HSA approval because the HSA announced that it would not approve anymore acute care beds in area hospitals. National Gerimedical filed suit, alleging violations of Sherman Act sections 1 and 2 and alleging that Blue Cross and the HSA conspired to refuse to deal with the hospital.

141. 479 F. Supp. 1012 (W.D. Mo. 1979).

142. 628 F.2d 1050 (8th Cir. 1980).

143. 101 S.Ct. 2415, 2422 (1981). The Court noted that the regulatory aspects of the NHPRDA were not in effect in Missouri because the state did not have a state Health Planning Agency with authority to review hospital construction. Since the activity therefore was purely private, Blue Cross could not demonstrate that applying the antitrust laws would "frustrate a provision of the (NHPRDA) or create a conflict with the orders of any regulatory body.

144. United Mine Workers v. Pennington, 381 U.S. 657 (1965); Eastern Railroad President's Conference v. Noerr Motor Freight, Inc., 365 U.S. 127 (1961); See also California Motor Transport Co. v. Trucking Unltd., 404 U.S. 508 (1972).

145. Eastern Railroad President's Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 144 (1961).

146. Feminist Women's Health Center, Inc., v. Mohammad, 586 F.2d 530 (5th Cir. 1978), cert. denied 444 U.S. 924 (1979). The physician and several other gynecologists sent a letter to the head of a public hospital's residency program in Jacksonville, Florida to discourage residents from working at a Tallahassee abortion clinic. The court held that since the recipient of that letter would not have performed any governmental function, attempts to influence him were not protected under the Noerr-Pennington doctrine.

147. The National Health Planning and Resources Development Act (NHPRDA) and its legislative activity contain numerous indications that Congress wished the HSAs to act upon the hospital industry's overcapacity and to take some of the actions in our hypothetical situation. One section, 42 U.S.C. Section 300K, specifies a number of priorities for health planning activities, including "the development of multi-institutional systems for coordination and consolidation of institutional health services (including pediatric, emergency medical, intensive and coronary care and radiation therapy services)."(emphasis added). Another section directs HSAs to "seek, to the extent practicable, to implement its HSP (Health Services Plan) and AIP (Annual Implementation Plan) with the assistance of individuals and public and private entities in its health services area. 42 U.S.C. Sections 3001-2(c)(1).

148. Havighurst, Deregulating the Health Care Industry, pp. 133-34.

149. H.R. Rep. No. 93-1640, 93rd Cong. 2d Sess. (1974); reprinted in 1974 U.S. Code Cong. & Ad. News 7842, 7983.

150. See Parker v. Brown, 317 U.S. 341 (1943); Cantor v. Detroit Edison Co., 428 U.S. 579 (1976).

151. Havighurst, Id.

152. Id., at 136-37. (Havighurst, Deregulating the Health Care Industry, pp.133-34.)

153. The Justice Department has taken a similar position in an opinion requested by an HSA about certain HSA activities. See, letter from Sanford H. Litvack, Assistant Attorney General, Antitrust Division, U.S. Department of Justice, in the Matter of Central Virginia Health Systems Agency, May 6, 1980.

154. Letter, cited n 153, supra. Emphasis added.

Section 4

1. See, e.g., Strunk v. Strunk, 445 S.W.2d 145 (Ky. 1969) (mentally incompetent adult allowed by court order to donate a kidney to his brother due in part to strong relationship between brothers and perceived harm to incompetent individual if brother died); Little v. Little, 576 S.W.2d 493 (Tex. Civ. Ct. App. 1979) (authorizing removal of kidney from fourteen year old with Down's syndrome for transplantation into brother); Compare, Lausier v. Pescinski, 226 N.W.2d 180 (Wisc. 1975) (no kidney removal allowed from mentally incompetent adult where he would gain no psychological benefit from donation). As to children without mental disability, see e.g., Hart v. Brown, 289 A.2d 386 (Conn. 1972) (kidney donation allowed). See generally, Annot., Transplantation: Power of Parent, Guardian, Committee to Consent to Surgical Invasion for the Benefit of Another, 35 A.L.R.3d 692.

2 See, e.g., Sirianni v. Anna, 55 Misc. 2d 553, 285 N.Y.S.2d 709 (1967) (mother who volunteered to permit one of her kidneys to be transplanted into the body of her adult son after defendant surgeons had negligently removed the son's kidneys could not recover from the surgeons for the resulting impairment to her health resulting from loss of one kidney); Moore v. Shah, 458 N.Y.S.2d 33 (App. Div. 1982) (Kidney donor (son) had no cause of action for negligent diagnosis and treatment of donee [father]).

3. However, the Act does not limit liability for treatment of the donor prior to death, or treatment of the live transplant recipient. Williams v. Hoffman, 66 Wis.2d 145, 223 N.W.2d 844 (1974).

4. See, Rose, "Medicolegal Problems Associated with Organ and Tissue Transplantations," 85, 91 in Cyril H. Wecht, Legal Medicine 1982 (1982); Jeddeloh and Chatterjee, Legal Problems in Organ Donation, 58 Surgical Clinics of North America 245, 248 (1978).

5. 66 Wis.2d 145, 223 N.W.2d 844 (1974).

6. See, e.g., Raab v. Casper, 124 Cal. Rptr. 590 (1975).

7. See also, Williams v. Hoffman, 223 N.W.2d 844, 76 A.L.R. 880, 887 (Wis. 1974).

8. The Act provides that a number of persons can be specified as the donee of the organ, such as the intended recipient. See section 3. If no donor is specified, the gift may be accepted by the deceased person's attending physician. However, the physician who becomes a donee in this manner cannot participate in the procedures for removing and transplanting a heart.

9. Section 2(c).

10. The Uniform Anatomical Gift Act, Section 6 outlines the means by which an anatomical gift may be revoked.

11. Such a suit would probably be grounded on a charge of interference with a corpse. See, e.g., Prosser, Torts, (4th Ed. 1971) 58, 59; 4 Restatement of Torts, sec. 868. See also, Koerber v. Patek; 123 Wis. 453, 102 N.W. 40 (plaintiff entitled to recover where defendant was given permission to examine the decedent mother's stomach but instead removed it).

12. Uniform Anatomical Gift Act Section 7(b). The comments to section 7(b) of the Act adopt the view that no clear cut definition of death can be formulated and that "no reasonable statutory definition is possible. The answer depends upon many variables, differing from case to case. Reliance must be placed upon the judgment of the physician in attendance."

13. Stason, The Uniform Anatomical Gift Act, 23 Bus. Lawyer 919, 928 (1968).

14. No. 2831 (Richmond, Va. L. & Equity Ct., May 23, 1972).

15. See, Va. Code Section 54.325.7 (Cum. Supp. 1981).

16. See, Dispute over "Death" Stirs Medical Debate, American Medical News Oct. 3, 1980.

17. 81 Misc.2d 1002, 367 N.Y.2d 686 (Sup. Ct. 1975).

18. N.Y. Pub. Health Law Article 43, Sections 4301-4307 (1977).

19. 367 N.Y.S.2d at 691.

20. See, Alabama - Ala. Code § 22-31-1-4(cum supp 1979); Alaska - Alaska Stat § 09.65.120(Cum Supp 1980); Arkansas - Ark. Stat. Ann. § 82-537-538 (Cum Supp 1981); California - Cal. Health and Safety Code §§ 7180-7182 (Deering Supp. 1980); Colorado - Colo. Rev. Stat. § 112-36-136 (1981); Connecticut Cum. Gen. Stat. Ann. § 19-139; (West Cum. Supp. 1981); Florida - Fla. Stat. § 382.085 (1980); Georgia - Ga. Code Ann. §88-1715.1 (Cum. Supp. 1980); Hawaii - Hawaii Rev. Stat. §327-C-1 (Supp 1980); Idaho - Idaho Code §54-1819; Illinois - Ill. Ann. Stat. Ch. 110 1/2 §302 (Smith Hurd Cum. Supp. 1978) (Effective Oct. 1, 1975); Iowa - Iowa Code Ann. §702.8 (West 1980); Kansas - Kan. Stat. Ann. §77-202 (Cum Supp. 1979); Louisiana - La. Rev. Stat. Ann §9.111 (West Cum. Supp. 1981); Maryland - Md. Ann. Code art 43§54F (1980); Michigan - Mich Stat. Ann. §14.15 (1021-24) (Cum. Supp. 1981); Montana - Montana Code Ann. § 50-12-101 (1978); Nevada - Nev. Rev. Stat § 451.007 (1979); New Mexico - NM Stat. Ann. § 12-2-4 (1978); North Carolina - N.C. Gen. Stat. § 90-323 (Cum. Supp 1979); Oklahoma - Okla. Stat. Ann. tit 63,

§ 1-103 West Cum Supp 1981); Oregon - Or. Rev. Stat. § 146.087 (1977); Tennessee; Tenn. Code Ann. § 53-459 (Cumm Supp. 1980); Texas - Tex. Rev. Civ. Stat. Ann. art 447t (Vernon Cumm. Supp. 1980); Virginia - Va. Code § 54-325.7 (Cumm. Supp. 1981); West Virginia - W. Va. Code § 16-19-1 (Supp. 1980); Wyoming - Wyo Stat. § 35-19-101 (Cum. Supp. 1979).

21. Several courts have recognized brain death standards in criminal homicide cases. See, e.g., State v. Fierro, 124 Ariz 182, 603 P.2d 74 (1979) (removal of respiratory life support system was not the proximate cause of gunshot victim's death); Commonwealth v. Goldston 373 Mass. 249, 366 N.E. 2d 744, cert. denied, 434 U.S. 1039 (1978) (adopting a brain death standard in criminal cases). Brain death standards have also been judicially adopted in several civil cases. See, e.g., Tucker v. Lower, No. 3831 (Richmond, Va. L & Eq. Ct., May 23, 1972) (wrongful death action involving claim of premature declaration of death of organ donor); New York City Health & Hospital Corp. v. Sulsona, 81 Misc.2d 1002, 367 N.Y.S.2d 686 (Sup. Ct. 1975) (Declaratory judgment on brain death standard under New York's, Anatomical Gift Act); In re Bowman, 617 P.2d 731 (Wash. Sup. Ct. 1980) (Judicial adoption of the Uniform Determination of Death Act).

22. See, President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Defining Death (1981).

23. See, eg., Kusanovich, Medical Malpractice Liability and the Organ Transplant, 5 University of South Florida Law Review 223, 250-53 (1971).

24. See, eg. Jeddeloh and Chatterjee, Legal Problems in Organ Donation, 58 Surgical Clinics of North America 245 (1978).

25. Id. at 248.

26. Williams v. Hoffman, 223 N.W.2d 844 (Wisc. 1974) (good faith exemption applies to (a) the mechanics of giving and receiving anatomical gifts (b) the determination of time of death, and (c) procedures following death.)

27. An early attempt to suggest guidelines for cooperation was made by the Commmittee on Forensic Pathology of the College of American Pathologists in 1969. The Committee put forth the following guidelines for determining when to permit organ retrieval prior to autopsy. They suggested that organ retrieval not be permitted prior to autopsy in cases of: (1) known or suspected homicide; (2) body trunk injuries when major organs are desired; (3) industrial accident; (4) suspected of poisoning; (5) possible medical malpractice cases; (6) two or more party vehicle accidents in which there are serious

questions of liability; and (7) apparent suicide in which there is serious suspicion of possible accident or involvement of another person. Committee on Forensic Pathology of the American College of Pathologists, Coroners Cases as Transplant Donors, 23 Pathologist 45-47 (1969).

28. See, Davis and Wright, Influence of the Medical Examiner on Cadaver Organ Procurement. 22 Journal of Forensic Science 324 (1977).

29. Texas Code Art. 49.29(6)(1977).

30. Health Law Center, II Hospital Law Manual (1983) §6-7.

31. See, e.g. Dunham v. Wright, 423 F.2d 940; Pegram v. Sisco, 406 F. Supp. 776, aff'd without op. 547 F.2d 1172; Young v. Group Health Cooperative, 85 W.2d 332, 534 P.2d 1349.

32. Wilkenson v. Vesey, 110 R.I. 606, 615, 295 A.2d 676 (1972).

33. See Campbell v. Olivia, 42 F.2d 1244; Bang v. Charles T. Miller Hospital, 251 Minn. 427, 88 N.W. 2d 186. See generally, Failure to Keep Up as Negligence, 224 Journal of the American Medical Association 10 (1961).

34. Moreover, the physician may be reluctant to refer a patient to a distant center. Cardiac transplant centers tend to be clustered in metropolitan areas on the two coasts. As a result, residents of large geographical areas currently do not have ready access to a transplant center. However, the large centers typically draw patients from all over the country (and the world). If the physician reasonably should know of the possibility of recommending the patient to a transplant center, then presumably lack of proximity to such a center should not be a decisive factor in determining whether the duty to inform exists. Whether the patient chooses to travel in order to seek treatment would likely be assessed as an issue involving personal considerations that falls within the patient's sphere of decisionmaking.

35. The physician may not tell an individual of the possibility of transplantation because he or she does not believe that the treatment is indicated for the particular patient. Case law has held that if the physician has a reasonable belief that an existing treatment would not work in a particular patient's case, the physician need not suggest it. Harrigan v. United States, 408 F.Supp. 177; Danner v. Vielleux, 322 A.2d 82. However, that belief must be reasonable, as indicated by the appropriate medical standard of practice. Therefore, whether or not the physicians' duty to inform is excused depends upon the reasonableness of the assessment that treatment is not feasible in light of the legally accepted level of medical practice. It is likely that the level of sophistication

required in making this determination will increase as transplantation becomes more widely accepted and acknowledged as a viable treatment alternative.

36. Holder, Physician's Failure to Obtain Informed Consent to Innovative Practice of Medical Research, 15 P.O.F.2d 711, 725.

37. Morrison v. McKillop, 17 Wash. App. 396, 563 P.2d 220.

38. Since the inception of transplantation programs, the shortage of donor organs has limited the number of transplantations that may be performed. The shortage of donor organs has led to a situation in which demand for the procedure outstrips the supply of transplantable organs. Waiting lists for many transplant programs have developed and may continue to grow as transplantation becomes more accepted within the medical community. A physician would undoubtedly argue either that no duty existed because there was no reasonable chance of acceptance into a transplant program, or that there is no causal relationship between the failure to refer and the harm to the patient, since there is no proof that the patient would have been accepted and would have survived surgery.

39. 211 N.Y. 125, 105 N.E. 92 (1914).

40. Id. at 129-30, 105 N.E. at 93.

41. See Note, Evolution of the Doctrine of Informed Consent, 12 Georgia Law Review 581 (1978).

42. Salgo v. Leland Stanford Jr., University Board of Trustees, 154 Cal. App. 2d 560, 317 P.2d 170 (1957).

43. Some jurisdictions, however, still treat the cases as arising out of the law of assault and battery.

44. There are two basic standards for determining a breach of duty in informed consent cases. The first standard is commonly known as the "professional standard". It is based on the notion that the duty of a physician is limited to those disclosures that a reasonable medical practitioner would make under the same or similar circumstances. See, e.g., Natanson v. Kline, 186 Kan. 393, 350 P.2d 1093, reh'g denied 187 Kan. 186, 354 P.2d 670 (1960).; Karp v. Cooley, 349 F. Supp. 827 (S.D. Tex. 1972), 493 F.2d 408 (5th Cir. 1974). The second standard, the "reasonable patient standard", bases the standard for disclosure on what the average, reasonable patient would want to know, rather than on what the average physician would disclose. See, Canterbury v. Spence, 464 F.2d 772, 780-84 (D.C. Cir. 1972). For a discussion of the two standards, see, A. Rosoff, Informed Consent: A Guide for Health Care Providers (1981).

45. See, Note, Informed Consent and Hospital Consent Forms: Paper Chasing in a Video World, 61 University of Detroit Journal of Urban Law 105, 107 (1983).

46. Capron, Informed Consent in Catastrophic Disease Research and Treatment, 123 University of Pennsylvania Law Review 340, 367-68 (1974).

47. Annas, Consent to the Anticipated Heart: The Lion and the Crocodiles, 13 Hastings Center Report, 20 (1983).

48. Gates V. Jensen, 92 W.2d 246, 595 P.2d 919, 922-23 (1979).

49. Rosoff at 43.

50. See, e.g., Holt v. Nelson, 523 P.2d 211 (W.Ct.App. 1974).

51. 464 F.2d 772, 783-84 (D.C.Cir. 1972), cert. denied 409 US 1064.

52. Id.

53. Id.

54. Cobbs v. Grant, 104 Cal.Rptr. 505, 515, 502, p.2d 1,11 (1972).

55. However, if a particular patient is proved to have been aware of certain risks, they cannot form the basis of a claim of nondisclosure.

56. Immunosuppression is accomplished by infusing the donor's tissue concurrently or properly timed with immunosuppressive drugs. There are three general groups of immunosuppressive drug regimens:

    (1) Antiproliferative, antimetabolic, and autimotic agents that act on cells in their reproductive cycle; examples include methotrexate, cyclophosphamide, and vincristine;

    (2) Agents that affect lymphoid tissue. Cyclosporine A is the most promising agent recently introduced; and

    (3) Agents with specific immunosuppressive properties. See, Floersheim, Pharmacologic Immunosupprossive Agents, 12 Transplant Proceedings 315-19 (1980).

57. Sheil, A.G.R., Transplantation and Cancer, in Morry, J.J. ED, Kidney Transplant (1969). The mechanisms leading to cancer in the recipient include altered immune surveillance and immunoregulation of oncogenic virus, genetic factors, chronic antigenic stimulation, and the neoplastic actions of

immunosuppressive drugs. Rose, Medicolegal Problems Associated with Organ and Tissue Transplants, in Wecht, C.H. Ed., Legal Medicine 1982, 85-100, (1982).

58. However, there is no obligation to inform the patient of risks that flow from an improperly executed medical procedure, and simply informing the patient that negligent acts may occur would not excuse the negligence.. See, e.g., McPhee v. Bay City Samaritan Hospital, 10 Mich. App. 567, 159 N.W. 2d 880 (1968) (when the result is unexpected and caused by alleged malpractice the lack of informed consent can not be proximately related to the plaintiffs injuries).

59. Kaufman, Consent and Adams, et al, Post-transplant Hypersplenism, Transplant Proceedings 96-99 (1979).

60. Bush, Category, Tiltiey, Variant Forms of Arthritis in Human Allografts, 11 Transplant Proceedings 100-103 (1979).

61. Ruderman, Poehling, Gray, et. al., Orthotropic Complications of Renal Transplant in Children, 11 Transplant Proceedings 104-106 (1979).

62. Pricontt, Huraux, and Jasmine, A Virological Study of Interstitial Pneumonia in Patients with Acute lymphoid leukemia Treated with a Combination of Methotrexate and 6 - Mercaptopurine, 13 European Journal of Cancer 479-82 (1977).

63. Capron, Informed Consent in Catastrophic Disease Research and Treatment, 123 University of Pennsylvania Law Review 340, 371 (1974). Use of new drug regimens will also involve FDA approval and Institutional Review Board procedures.

64. Obviously, newer programs will have to rely upon information gleaned from other centers. However, it may be more accurate, if enough data have been generated, to use the transplant center-specific information, since centers may vary considerably in their success rates. A problem with this approach, however, is that the figures may not reflect information about the center's "real" rate of success, because there are no controls for the sickness of the patients when they are transplanted.

65. Legal liability for overstating the odds of successful results could be argued on the basis of breach of contract as well as on informed consent. A physician who "guarantees" results can be sued for breach of contract for failure to produce what was promised. Damages in such cases are not based upon the pain the patient suffers, but instead are based upon the difference in value between the result promised and that actually delivered.

The breach of contract theory is best illustrated by the classic case of Hawkins v. McGee. 84 N.H. 114, 146 A. 641 (1929). In Hawkins, a surgeon promised that he could perform a skin graft to

replace scar tissue in a boy's palm that would leave the boy with a "one hundred percent good hand." The surgeon took the graft tissue from the boy's chest. A short time later, of course, the palm began to grow dense, matted hair. The trial court denied any recovery, since the boy had not shown that the surgeon had been negligent or that having hair on one's palm was any worse than having scar tissue. The appeals court reversed and explained that the proper question was whether the physician had made good on his promise. The measure of damages, the court announced, was the difference in values between the promised "perfect" hand and the hairy one delivered.

The key to Hawkins was the unconditional nature of the promise of good results. In general, however, courts are reluctant to use contract theory in medical treatment cases.

66. See, e.g., Rosoff, Informed Consent (1981), at p. 51.

67. Arnold J. Rosoff , Informed Consent (1981).

68. See, e.g. Karp v. Cooley 493 F.2d 408, 422 (1974) (No proof that heart transplantation and mechanical heart recipient would not have consented had alleged disclosure materials been alleged).

69. J. Katz & A. Capron, Catastrophic Diseases: Who Decides What? 82 et seq (1975).

70. For a general discussion of the issue of informed consent, see, President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral research, Making Health Care Decisions, Vol. 1 (1982) p. 17.

71. Contact and communication with the patient and the patient's family can help decrease the incidence of litigation. Gregory, Medical Malpractice Prevention, in Cyril Wecht, Legal Medicine 1982, 177,182.

72. In almost all cases of malpractice the plaintiff must present expert medical testimony as to the applicable standard of care, and any deviation from that standard that has occurred in treatment of the patient. Where a legitimate, but not yet widely used procedure is involved, it may be difficult to obtain the testimony of an expert in the field because their numbers are small, and the professionals may be unwilling to testify in court. A good example is one of the few reported cases involving heart transplantation and an artificial heart. In Karp v. Cooley, 349 F.Supp. 827 (S.D. Tex. 1972), 493 F.2d 408 (5th Cir. 1974), one of the chief obstacles to proving a claim of lack of informed consent to implantation of an artificial heart, and malpractice in the course of treatment, was lack of expert medical testimony at trial. At the time of the suit, Texas law required that the standard for informed consent be established

through expert opinion of what a reasonable medical practitioner in a similar community and of the same school of medical thought would have disclosed to the patient regarding the proposed treatment. 493 F.2d 420-21.

73. See, Baumgartner et al, Cardiac Homotransplantation, 16 Current Problems in Surgery 2 (1979).

74. Karp v. Cooley, 349 F.Supp. 827 (S.D. Tex 1972), aff'd 493 F.2d 408 (5th Cir. 1974). In 1969, Haskell Karp was referred by his Chicago physicians to a Texas heart surgeon, Dr. Denton Cooley, for treatment of severe cardiac disease. Upon his admission to the Texas hospital, Mr. Karp initially rejected a recommendation by Dr. Cooley that he undergo a heart transplantation. Mr. Karp instead opted for a "wedge procedure" in which tissue from the diseased ventricle is removed so that the remaining tissue can function at its optimal level. The written and witnessed consent to this procedure stated, however, that if death appeared imminent, Mr. Karp's heart would be removed and a mechanical substitute used until a donor heart became available. The mechanical heart had, at that time, been used only in animal experiments. Dr. Cooley also testified that he obtained verbal consent as well. Although Mrs. Karp also signed the consent form, there was conflicting testimony as to what Cooley told her about her husband's condition and proposed treatment. Medical testimony established that during the procedure, Mr. Karp's heart was failing, and therefore Dr. Cooley removed the heart and implanted the first artificial heart to be used in a human in Haskell Karp's chest. Mr. Karp survived for 64 hours after surgery. During this time, Mrs. Karp and Dr. Cooley made public pleas for a cardiac donor. A donor heart was found, and was implanted, but Karp died on the day after the transplant. The autopsy attributed his death to bronchopneumonia and acute kidney failure. Mrs. Karp later filed suit against Dr. Cooley and his assistant surgeon for damages and wrongful death. She (and her sons) alleged that neither she nor her husband had been told about the number of animals on which the artificial heart had been tested nor the results of those tests, or of the serious risk of injury involved in use of the artificial heart, or that it was experimental. She also contended that Dr. Cooley had failed to tell her husband that another surgeon had said that Mr. Karp was not a good candidate for surgery. She therefore claimed that the consent was fraudulently obtained, that the surgery was negligently performed, and that by fraudulent and deceptive practices Mrs. Karp was used by the defendants to secure a human heart donor.

The trial court gave a directed verdict for the doctors, largely on the basis that the Mrs. Karp had not produced expert medical opinion to establish any of her claims. As such, the trial court never faced some of the more complex issues of causation and damages that would have been presented if the plaintiff had

obtained sufficient evidence of a standard of care and breach of that standard by the doctors. On appeal, the Fifth Circuit Court of Appeals ruled on alternative grounds that an informed consent claim could not be established because of lack of evidence of any causal connection between lack of informed consent and harm, since there was no evidence that the use of the mechanical heart had caused Mr. Karp's death, and that Mr. Karp would not have consented had the alleged undisclosed risks been disclosed. 493 F.2d at 422.

75. See, e.g., McDermott v. Manhattan Eye, Ear & Throat Hospital, 26 App. Div.2d 519, 270 N.Y.S.2d, 955, aff'd without op. 18 N.Y.2d 970, 278 N.Y.2d 200, 224 N.E. 2d 717 (1966) (plaintiff contended that cornea transplant that later failed was contraindicated - court held in part that where an unsuccessful operation could produce no worse result than the result that would ensue if nothing were done, an expectation of success even less than that which might be anticipated under favorable circumstances warranted going ahead).

76. See, e.g. McDermott v. Manhanttan Eye, Ear & Throat Hospital, 26 App. Div. 2d 519 (1966) (no evidence cornea transplant surgeon lacked necessary level of skill claim of negligent selection against hospital rejected).

77. Copeland & Stinson at 13-15.

78. For a collection of case law, see, Annot. Liability of Hospital, Physician, or other Individual Medical Practitioner for Injury or Death Resulting from Blood Transfusion, 20 A.L.R. 4th 136.

79. Sheil, Transplantation and Cancer in Morris PJ Ed, Kidney Transplantation (1979) P. 335.

80. But see, Helling v. Carey, 83 W.2d 514 (1974) (standard adopted by the profession itself can be found to be negligent.); Harris v. Groth, _____ W.2d_____ (1983) (health care provider must exercise that degree of care possessed by the reasonably prudent practitioner possess the same degree of skill, care and learning possessed by other members of the profession in the State).

81. Williamson v. Numerical Hospital of Bay County, 307 So.2d 199 (Fla. App 1975) (Advisory opinion).

82. Glabori v. Peters, 127 Conn. 380, 16 A.2d 833.

83. Warvel v. Michigan Community Blood Center, 74 Mich. App. 440, 253 N.W.2d 791 (1977); Balkowitch v. Minneapolis War New. Blood Bank, Inc., 270 Minn. 151, 132 N.W.2d 805 (1965).

84. States use various ways in which to define standard of care. Some are "local", some are statewide, and some are national - in

an area like transplantation, many would probably follow recent trends and use a national standard and look to the standard of care exercised by the national transplant community.

85. Toledo-Pereyra, LH, Organ Harvesting, in LH Toledo Pereyra, ed., Basic Concepts in Organ Procurement, Perfusion and Preservation for Transplantation (1982). It is currently felt that, due to the shortage of organs, donors with primary intercerebral tumors or low grade skin cancers may be accepted since the possibility of mestastises from these cancers is remote. Sheil, Transplantation and Cancer, in Kidney Transplantation (1969).

86. Toledo-Pererya at 57-58, Copeland and Stinson at 12-14.

87. Toledo-Reverya at 57-59; Copeland & Stinson, at 12-14.

88. Id. at 13-15.

89. 63 Mich. App. 79, 234 N.W.2d 411 (1975).

90. 234 N.W.2d at 414.

91. 234 N.W.2d at 414.

92. See, e.g., Grabori v. Peters, 127 Conn. 380, 16 A.2d 833 (1940) (failure to test transfused blood for syphillis when adequate tests are available constitutes malpractice).

93. Sheil, supra; Copeland and Stinson, 40-41.

94. Sheil, supra at 347.

95. Plaintiffs in several cases involving blood contaminated with serum hepititus asserted liability based upon an implied warranty. The relevant UCC provisions are 2-314 -- pertaining to an implied warranty of merchantability (covers fitness for ordinary uses); and 2-315 -- dealing with the implied warranty of fitness for particular purposes. The UCC applies directly only to sales of goods not services, and many cases argued on this theory focus on the question of whether providing blood constitutes a "sale." However, some courts have extended the UCC warranties to provision of services by analogy. Other cases allege strict liability in tort for sale of an unreasonably dangerous product. The Restatement of Torts 2d, §402A provides that one who sells any product in a defective condition, unreasonably dangerous to the user or consumer or to his or her property, is liable if (a) the seller is engaged in the business of selling such a product and (b) the product is expected to, and does, reach the user or consumer without substantial change in the condition in which it was sold. The rule applies even though the seller has exercised all possible care and preparation in the sale of the product, and the user or consumer

has not bought the product from, or entered into any contractual relation to the seller.

97. 47 Ill.2d 443, 266 N.E.2d 897 (1970).

97. Id. This decision has since been effectively overturned by statute. See, Illinois Ann. Stat. tit 91 Sec. 182-3 (1971).

98. Hoffman v. Misericordia Hospital of Philadelphia, 439 Pa. 501, 267 A.2d 867 (1970). Again overturned by statute, Pa. Stat. Ann. Art. 35 Sec. 10021 (1972).

99. Belle Bonfils Mem. Blood Bank v. Hansen, 579 P.2d 1158 (Colo. 1978). The court noted that hospitals have generally been relieved of liability because a hospital's sale of blood is incident to providing medical services. The blood bank's liability was based on the theory that it was selling a product, i.e., blood, and was not supplying medical services.

100. 2 S.B. No. 694 (Laws 1981). Some states that have enacted legislation rejecting strict liability do not cover commercial blood banks. See, e.g., R.C.W. 70.54.120. (Washington state).

101. See, e.g., Shepard v. Alexian Bros. Hospital, Inc., 33 Cal.App. 3d 606, 109 Cal. Rptr. 132 (1st Dist. 1973); St. Luke's Hospital v. Schmaltz, 188 Colo. 353, 534 P.2d 781 (Colorado 1975); Fisher v Sibley Memorial Hospital, 403 A.2d 1130 (Dist.Co.App. 1979); Russell v. Community Blood Bank, Inc., 185 So.2d 749, cert. denied 196 So.2d 115 (Fla. 1966); Lovett v. Emory University, Inc., 116 Ga.App. 277, 156 S.E.2d 923 (Georgia 1967); Glass v. Ingalls Memorial Hospital, 32 Ill.App.3d 237, 336 N.E.2d 495 (Illinois 1975); Juneau v. Interstate Blood Bank, Inc., 333 So.2d 354, cert. denied, 337 So.2d 220 (Louisiana 1976); Warvel v. Michigan Community Blood Center, 74 Mich.App. 440, 253 N.W.2d 791 (Michigan 1977); Perlmutter v. Beth David Hospital, 308 N.Y. 100, 123 N.E.2d 792, reh. denied, 308 N.Y. 812, 125 N.E.2d 869 (New York 1954); St. Martin v. Doty, 493 S.W.2d 95 (Tennessee 1972); Foster v. Memorial Hospital Asso., 219 S.E.2d 916 (West Virginia 1975); Koenig v. Milwaukee Blood Center, Inc., 23 Wis.2d 324, 127 N.W.2d 50 (Wisconsin 1964).

102. 308 N.Y. 100, 123 N.E.2d 792, reh. denied, 308 N.Y. 812, 125 N.E.2d 869 (1954).

103. Ill. Rev. Stat. Ch 91 §§181 et seq (1977). These types of statutes have survived constitutional challenges under equal protection and special legislation theories. See, e.g., Bingham v. Lutheran Gen & Decemers Hospitals, 34 Ill.App.3d 562, 340 N.E.2d 220 (1975).

104. Mich. Stat.Ann 14.528(1).

105. Of course, difficulties will still be encountered in proving causation and damages.

106. Kan. Stat. Ann. §77-202 (Supp. 1971).

107. Md. Code Ann., Art 43, §54-F(1972).

108. N.M. Stat. Ann. §12-2-4 (1978).

109. Va. Code §325-7 (1979).

110. Okla. Stat. Ann. tit. 63, §1-301(g) (West 1975).

111. The proposal first appeared in Capron and Kass, A Statutory Definition of the Standards for Determining Human Death: An Appraisal and a Proposal, 121 University of Pennsylvania Law Review 87, 102-104 (1972).

112. (See, Capron, Legal Definition of Death, 315 Annals of the New York Academy of Science 349, 356 (1978).

113. See, Alaska Stat. §09.65 120 (Cum. Supp. 1979); Iowa Code Ann. §702.8 (West 1979); La. Rev. Stat. Ann. §9:111 (West Cum. Sup. 1980); Mich. Stat. Ann. §14.15 (1024) (1979). Others have made more substantial modifications. See, Ala. Code §§22-31-1 to 22-31-4 (Cum. Supp. 1979) (accepts other, unspecified procedures; provides for "independent confirmation of death" by a second doctor when brain criteria are used or transplantation is planned; excludes liability for actions in accordance with statute); Hawaii Rev. Stat. §327 C-1 (Supp. 1979) (requires opinion of a consulting physician for brain-based determinations; provides for biennial review of subject by committee appointed by director of health); Tex. Rev. Civ. Stat. Ann. art. 4447t (Veron Cum. Supp. 1980) (adds "no liability" provisions of AMA model bill).

114. 100 A.B.A. Ann. Report, 231-32 (1975) (Feb. 1975 Midyear meeting).

115. See, Mont. Rev. Code Ann, §50-22-101 (1977); and Tenn. Code Ann. §53-459 (1976).

116. See, Ill. Ann. Stat. Ch. 3, §552 (b) (Smith-Hurd Supp. 1975).

117. 12 Uniform L. Ann. 15 (1981).

118. See, Nev. Rev. Stat §451, as amended by SB 5(Laws 1979).

119. See, W. Va. Code §16-19-1 (Supp. 1980).the part of involved health care practitioners or institutions would be a likely subject of litigation.

120. See W. Va. Code §16-19-1(c) (Cum. Supp. 1977) (adopted March 9, 1975).

121. President's Commission report at 109 as amended at the December 1979 Interim Meeting of the AMA, the proposal incorporated cardiopulmonary and brain-based alternatives for declaring death. See, 243 A.M.A. 420 (1980) (External).

122. President's Commission report, at 66-67.

123. President's Commission Report at 119.

124. Colo. Rev. St. §12-36-136 (1981); Idaho Code §54-1819 (Cum. Supp. 1981); (defines "accepted medical standards" as "the usual and customary procedures of the community").

CHAPTER 35

AN OVERVIEW OF THE ETHICAL ISSUES

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A. INTRODUCTION

1. PATIENT SELECTION

During the last half century, progress in medical treatment and medical technology created situations in which only some, among many in need, were able to receive new forms of therapy. Development of effective anaesthetics, the discovery of insulin and penicillin are historical instances of this allocation of scarce resources (Beecher, 1969). Factors such as the limited amounts of required substances, paucity of trained personnel, absence or inadequacy of information about the new forms of treatment, strained finances, etc., forced choices about how the limited resource should be made available. Often, these choices were made informally; treatments were provided in the few places where the advances had been made and to patients who, almost by chance, happened to be in those places or who were sent by the few physicians cognizant of the developments. In the case of antibiotics used in theaters of war, for example, distribution policy was based on traditional rules of military triage (Winslow, 1982:8).

In the late 1960's hemodialysis was introduced as a life-sustaining therapy for persons suffering from otherwise fatal kidney disease. The skill and technology required for this procedure were possessed by individuals located in a very few medical centers. These centers were forced to select a small number of patients from among the many thousands throughout the United States who might have benefited from treatment (Katz and Proctor, 1969). The approach to the problem of patient selection devised by one center, the Northwest Kidney Center in Seattle, became widely known as the result of an

article in Life Magazine (Alexander, 1962). This approach used a lay committee who screened candidates according to non-medical criteria, including "social worth". The ethics of this system and of possible alternatives were widely debated in the press and by scholars. Furor over the shortage of treatment and the need to select among needy victims of end-stage renal disease (ESRD) eventually led to enactment of the End Stage Renal Disease Program by Congress in 1972 (Rettig, 1980). Renal transplantation, a parallel therapy for ESRD, also necessitated allocation of a scarce resource with an additional complication of a scarcity of matching organs. The ethics of selection of patients for a scarce resource has been discussed largely in the context of these two technologies (and, to some extent, the analogous technology of cardiac transplantation). The literature produced on the subject is ample, and several fundamental opinions have emerged. These varying opinions will be reviewed in Chapter 36, their strengths and weaknesses pointed out, and the areas of agreement and disagreement indicated.

Establishing ethical criteria for treatment is not an unusual issue, nor does it arise only in dramatic cases. Since antiquity, physicians have had to allocate their attention among persons seeking their help. That care should be for the most seriously afflicted before those less ill or wounded is a traditional rule revealing a moral evaluation of the problem. Throughout the ethical literature of medicine, one finds allusions to physicians who choose patients because of their social class, religion, or financial status rather than simply on the basis of their petition for help or their medical

need. These sorts of discriminations are usually, though not always, condemned as unethical. One also finds occasional reference to the reprehensible practice of providing medical or surgical treatments to persons who do not really need them; in such cases, the criteria for appropriate treatment are ignored or abused. In general, the ethical physician would be expected to conform to certain criteria in employing his or her medical skills; the principle criterion would usually be demonstration of some recognized form of medical need. These recognized forms of medical need were described in the medical literature of the time. Thus, setting criteria for ethical patient selection, and the invocation of these criteria to praise or blame the physician, is not a stranger to medical ethics (Reiser et.al., 1977).

Furthermore, an individual's need for medical care is not the only factor that dictates its availability. Many other factors are pertinent. The unsystematic distribution of physicians, hospitals, transportation, etc. means that some persons with genuine medical need will not obtain treatment because they are not at the right place at the right time. The differing ability of persons to enter and move through the medical care system means that some persons, less capable or less well situated, will not make the right connections. They may not know that they need help or how to get it; they may get it only in inadequate and insufficient ways. In many nations, the economic structure of health care means that some persons, whose ability to pay the doctor or to buy insurance is limited, may be unable to obtain care. In the United States, between 22 and 24 million people do not have health insurance. Many such persons, for various reasons, may be

ineligible for the public programs designed to make care available. Thus, ethical questions have been raised about the impact of social class, economic status, and geographical location on the availability of health care. Although the dominant opinion in the ethical literature affirms that "ability to pay" should not serve as a criterion for acceptance into medical or health care, the debate over the universal right to health care is unresolved
and the actual provision of health care is still shaped in large part as a private enterprise system (President's Commission, 1983; Outka, 1974).

In other words, the debate about selection of patients for certain sorts of health care recognizes that health care in general is marked by major inequities. The effect of these inequities was illustrated by the one substantial effort to alleviate the selection problem, the ESRD Program, which focused on one disease and provision of its two therapies without regard to the general problem of availability of other types of health care. The result has been the creation of a very costly program that serves relatively few sufferers and excludes many other persons who suffer from equally life threatening diseases and who could benefit from a life saving technology. Thus, the problem of selecting patients for a certain sort of therapy cannot be divorced from the broader picture of the health care system generally. The Totally Artificial Heart Assessment Panel (National Institute of Health, 1972:19) recognized this connection when it struggled with the problem of how the highly technological and costly artificial heart could be made available to

those in need. The Panel wrote, "the high costs of clinical application of the artificial heart may force consideration of means (e.g., private or governmental insurance coverage or direct government funding)for making implantation available to all who need it without regard for ability to pay and may lead to broader reconsideration of the financial mechanisms for delivery of health services generally" (p. 191).

Thus, the ethical discussion raised by selection of patients takes place within the larger discussion of the distribution of health care generally. Selection of some patients and rejection of others is a choice forced not only by finite conditions of persons and institutions, but also by certain cultural, social and economic features of health care. Some of these features are amenable to policy change, others are very deeply rooted in broader realities.

Nevertheless, it is possible to take a more restricted view, given the current realities of the system. It is possible to ask, whether this particular treatment can be fairly distributed when it is not possible, under constraints of scarcity, to provide it to all who might benefit from it.

Another prefatory remark must be made: the term "selection of recipients" requires some explanation. In one sense, physicians select certain persons for certain treatments because they judge these persons to have an illness for which the treatment is indicated. Such judgments are complex, but they have at their center an understanding of the scientific and medical reasoning that relates illness and treatment. Selection of this sort goes on constantly and is not

generally ethically problematic. In another sense, selection refers to policies that include or exclude persons from certain sorts of treatment and to the mechanisms devised to implement these policies. Selection of this sort takes place in many ways. A county hospital may have a policy of accepting as patients only residents of that county. The Veterans Administration may provide care only for "service related disorders". Utilization review procedures may list reimbursement for certain treatment or for certain lengths of stay in hospitals. Insurance policies may exclude certain conditions or persons of a certain sort from coverage. At this level, selection becomes more centralized, more removed from the personal level of the patient-physician relationship.

For purposes of the current discussion, selection refers to the second sort of activity: policy and the mechanisms for its implementation. This raises another question: how and by whom are such policies set and administered. In the United States, centralized decision making about health care rarely occurs at all, let along about selection of patients for certain treatments. American health care is a complex mix of public and private activity and federal, state and local resources. This mix exists at all levels of provision, organization and financing. The establishment of a centralized decision making capability in the midst of this diversity is difficult, if not impossible. Thus, the practical aspects of implementing any particular recommended approach must be considered as the opinions about the ethics of selection are reviewed. However, that task is reserved for policy makers: this discussion is limited

to a review of the ethics, not the economics, policy, or organization of cardiac transplantation.

A final prefatory remark is of utmost importance. This discussion about the ethics of selection presupposes that cardiac transplantation has been proved to be an efficacious therapy for end stage cardiac disease. We assume the viewpoint of persons faced with the task of devising an ethical policy for distribution of a health care resource generally acknowledged by physicians as a useful therapy and sought by patients as a benefit for health. In light of this assumption we say very little about the selection problem during an experimental phase. We do not discuss at length how patients should be selected in view of providing safety, efficacy, and affordability. A few remarks at the end of Chapter 36 touch on this problem, but, on the whole, we review, as does most of the literature, the ethics of distributing a proven therapy in short supply.

2. ETHICAL ISSUES: DONORS, RECIPIENTS AND PROVIDERS

In the following chapters, the ethical issues raised by allocation of resources for cardiac transplant are reviewed. In addition to large questions of social justice and fairness that appear in these issues, there are a number of questions that more closely concern three principal actors in the drama of transplantation: the donors, the recipients, and the providers. These issues are discussed in Chapter 37. Some of these have been thoroughly examined in the ethical literature and in public discussion and considerable consensus has been reached about them. These include, for example, the definition of death for the purpose of removal of organs and the moral

requirement of informed consent by donors and recipients of organs. Other issues have received much less attention; some because, although they may become matters of great importance for public policy, they have not yet been forced to that degree of public attention required to attract the attention of ethicists. Chapter 37 will review the issues by stating the opinions found in the ethical literature where these exist.

One of the earliest debates in the modern renaissance of medical ethics argued the ethics of removal of organs for transplantation. The dramatic episodes of cardiac transplantation in South Africa in 1968, together with the less dramatic but extraordinary accomplishment of renal transplantation, called attention to the problem of how transplantable organs would be obtained. Cardiac transplantation required removal of an organ necessary for the continued life of the donor; renal transplant sought organs either from living donors or from those who were, in some sense, dead. One of the first international conferences on medical ethics was devoted to these issues (Wolstenholme, O'Connor, 1966).

The predominant ethical issue raised about removal of the heart is the moral requirement that the person from whom the organ is taken be dead. The removed organ must be viable, in the sense that it retains those biological properties that will enable it to function within the recipient. Thus, the body of the donor must still have some sort of vitality at the time of removal. At the same time, removal of the heart renders continued life impossible (unless another organ or artifical prothesis replaces it). Removal of a heart from a

living human would appear to be homicide in the moral and legal understanding of that term. Yet removal of a heart from a cadaver in which the vital functions, particularly perfusion of all organs by oxygenated blood, have totally ceased, might provide an organ too damaged for transplantation. Death, it appears, is an either/or proposition: one could be almost dead or recently dead but not, it seemed to most commentators, partially dead and partially not dead. Thus, the first attempt to grapple with this problem, "A Definition of Irreversible Coma: Report of the Ad Hoc Committee of Harvard Medical School to Examine the Definition of Brain Death," opens with the remark that their revision is prompted by the belief that "obsolete criteria for definition of death can lead to controversy in obtaining organs for transplantation" (Harvard Medical School, 1963).

Indeed, there was controversy; the literature of medical ethics is filled with it in the late 1960's and early 1970's. During the previous decades, it had become possible to maintain vital functions by mechanical support. At the same time, the ability of physicians to diagnose severe destruction of the brain had increased. Thus, the way out of the impasse appeared to be by devising a "new" criterion for determining death. The "old" criterion had relied on the clinical perception that the heart and lungs had apparently ceased to function because heart beat, pulse and breathing had stopped. The "new" criterion would rely on the clinical perception, assisted by the technique of encephalography, that the electrical activity of the brain had ceased. On the basis of this "new" criterion, an individual might still have heart beat and respiration caused by mechanical

support and, at the same time, be declared "dead" because no brain activity was detectable. From this point of view, "partial" death seemed possible; an individual could be dead in the brain but still living in the rest of the body. If medical practice would adopt this approach and if the law could be brought to sanction it, vital organs could be removed from "dead" bodies.

Although this approach was filled with ambiguities, states began to enact "brain death" statutes to replace or supplement their "obsolete" cardio-respiratory statutes. Peculiar legal cases appeared in the courts. Trauma services hesitated to cooperate with transplant services. Philosophers argued about the conceptual features of the new standard. Medical practictioners were uncertain of the differences between total brain death and permanent coma or vegetative state. The media reflected the doctors' confusion. In 1978, the Congress of the United States created the President's Commission for the Study of Ethical Problems in Medicine and in Behavioral and Biomedical Research. The enabling legislation directed the Commission to study, "the ethical and legal implications of the matter of defining death, including the advisability of developing a uniform definition of death" (42 U.S.C. Section 1802 (1978).

The Commission published its report, Defining Death, in July, 1981. After an extensive review of the theological, philosophical, legal and medical literature, and wide consultation with experts and with the public, the Commission recommended that legal jurisdictions enact the following Uniform Determination of Death Act (President's Commission, 1981:2):

> An individual who has sustained either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards.

This formulation expressed the Commission's conclusion that death should be considered a unitary phenomenon that could be accurately demonstrated either on the traditional grounds of irreversible cessation of heart and lung function or on the basis of irreversible loss of all functions of the entire brain. Underlying this conclusion was the position that death takes place when an organism loses its intrinsic capability to organize its own vital activities. Destruction of the entire brain, including brain stem, would bring about such a loss. Since respiration can be maintained externally by artificial systems, organic activities can be maintained even when the brain is totally destroyed. This, however, is not "being alive" as an individual.

"Brain death" then, consists of the disintegration of the organism due to destruction of certain integrating centers in the cerebellum and brain stem. The term should not be applied to the destruction of those parts of the brain, particularly the cerebral cortex, which govern consciousness and whose destruction causes the individual to lapse into an irreversibly comatose state. In such cases, cardiopulmonary activities may continue as integrated functions. Such a person is "alive" from the legal and ethical point of view, although apparently without consciousness or sensation and removed from further communication with the external world. The Commission

suggested certain clinical signs that should be used to diagnose and differentiate the first condition from the second. It proposed that medical practice recognize this distinction and make use of it to determine that death has occurred. It also recommended that legislatures enact statutes that acknowledge this standard of medical practice for the purpose of legal declaration of death.

The Commission Report represents a consensus about the issue of determining death. The consensus arises from the broad testing of opinion of experts in theology, philosophy, law and medicine, from the extensive discussion of the issues by a public body and from the almost unchallenged acceptance by professionals and by the public of the Commission's Report. At this writing, some 34 state legislatures have enacted the Commission's Recommended Uniform Statue, either as new legislation or by amending earlier statues.

In some states political obstacles remain. New York State, for example, does not yet have brain death legislation. It does, however, permit the taking of organs for transplantation from patients who are brain dead, in spite of the legal definition of death that obtains for other purposes. Even where such obstacles exist, the advantages of this legislation for clarifying a most troubling legal situation and for providing benefits to those in need advise its passage.

The broad consensus regarding brain death, however, should not obscure the persistence of several minority viewpoints (Bernat, Culver, Gert, 1981). One of these is a philosophical view that asserts that death properly consists of the loss of personality and

that this loss takes place when an individual can no longer interact with the environment. Solid arguments are made to this effect by some philosophers (Veatch, 1975; Green, Wikler, 1980). It seemed to the Commission, however, that if such a position were adopted, individuals in persistent coma would be considered dead and treated as dead, and thus it would be legitimate to remove organs from such individuals. It seemed to the Commission that, regardless of strong arguments, doubt remained about the theoretical issues and practical wisdom of endorsing such a position (President's Commission, 1981).

A second divergent opinion is represented by certain orthodox Jewish scholars who affirm on the basis of scripture and tradition that death takes place only when respiration and corporeal blood flow ceases (Bleich, 1979). The Commission, while respecting this position, did not judge it suitable to make exception in legal formulation for it, since individuals who believe in this position can request, for themselves and their family, that cardio-respiratory criteria alone be employed to determine death. However, even in this tradition, some scholars are willing to interpret the tradition in ways that permit the validity of the brain death criteria (Tendler, 1978).

Once the distinction between total brain death and persistent coma has been established in conceptual and clinical terms, the question can still be asked whether it is ethical to remove the heart from persons in persistent coma for purposes of transplantation. Presumably, if no ethical objection were raised to such a practice, legal authorization could be obtained by statute. Gaylin (1974) examined this possibility in a widely noted article, "Harvesting the

Dead," and suggested that the proposed benefits would not surpass the costs in intangible effects on our sense of human dignity and respect. A theologian, William May (1979) and a philosopher, Hans Jonas (1974), are cited in support of his opinion. More recently, Ralston argues against the "vivisection" of an irreversibly comatose person for purposes of transplantation. He proposes that whatever is biologically vital has ethical value and that there is an obligation to respect the body that is still fighting death: "part of the dignity of a living body is revealed in its sustained resistence to death" (Rolston, 1982:337). There has not been any strong argument to the contrary in the ethical literature, although the arguments of those philosophers who maintain that loss of personal identity should be counted as the death of the individual would appear incompatible with Ralston's thesis. Even these other philosophers, however, might find the practice of "vivisection" of the irreversibly comatose ethically unacceptable on other grounds, such as the possibility of including more and more sorts of "incompetent" persons into the category of "donors." In general, the ethical literature does not favor the proposal of "harvesting" the irreversibly comatose for cardiac transplantations.

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CHAPTER 36

SELECTION OF RECIPIENTS FOR CARDIAC TRANSPLANTATION

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A. REVIEW OF OPINIONS ABOUT THE ETHICS OF SELECTION

Shana Alexander's article in Life, "They Decide Who Lives, Who Dies," (Life, Nov. 9, 1962), reported on the selection system at Seattle's Northwest Kidney Center where chronic hemodialysis was first developed by Dr. Belding Scribner. Faced with the prospect of being able to serve only a handful of many desperate patients from around the country, the Center established a committee to select the fortunate few. While the committee was given relatively clear criteria for "medical" suitability (e.g. over age 45 and children would not "do well"), it soon found itself faced with agonizing choices between many medically suitable candidates. They began to try to sort out these competing candidates by assessing their social qualities and their past and future contributions to their families and to society. It became clear that such a process was practically impossible and ethically invidious (Fox and Swazey, 1974, Chapters 8-10). A law review article by Sanders and Dukeminier (1968), was the earliest analysis of the practice of patient selection on the basis of social worth. They noted that this practice, as exemplified in the Seattle Program, led to "a disturbing picture of the burgeoisie sparing the bourgeoisie." They concluded that "justice requires that selection be made by a fairer method than the unbridled consciences, the built-in biases and fantasies of omnipotence of a secret committee."

In the wake of this experience, the ethics of selecting persons to receive a life-saving medical technology have been thoroughly discussed in the literature of bioethics. Philosophers have taken note of the problem of personal agony experienced by the Seattle Panel and the

problem of bias noted by Dukeminier and Sanders. Before reviewing the particular arguments of the bioethicists, it should be noted that the discussions about selection for a scarce resource take place against a background discussion about the right to health care itself. Bioethcists are in general agreement that all persons should enjoy equal acess to needed care; they are in wide disagreement about how to define equality of access and needed care, as well as about the mechanisms whereby equal access could be achieved.

Against this background of general agreement about the right to equal access and its ethical justification, the more particular question about selection of patients for a life-saving scarce resource is debated. The ringing affirmation of theologian Paul Ramsey, "the equal right of every human being to live and not relative personal social worth should be the ruling principle," (Ramsey, 1970), arouses little dissent from ethicists. In one form or another, the principle of human equality holds a place of prominence in almost every modern theory of ethics. Also, commentators on social mores have noted that, fundamental ethical principle or not, equality is a myth vital to the stability and coherence of our society. To repudiate it openly, especially in the dramatic and radical matter of offering or withholding the very means of continued life, is ethically repugnant and socially intolerable.

However, as all who have studied the problems of equality and justice know, it is one thing to affirm the equality of all humans and quite another to say what equal treatment means. It is clear, philosophers commonly say, that <u>equal</u> treatment does not mean the <u>same</u>

treatment; at best, it means the same treatment in relevantly similar situations. The ethical problem is to define what a relevantly similar situation is and discern when one, in fact, exists. Moral and political philosophers have long attempted to do this in the areas of politics and education, but only recently have they sought to do so in health care (Daniels, 1981; inpress).

In that discussion there is hardly any dissent from the proposition that, as Williams (1971) states, "the proper (ethical) ground for the distribution of medical care is ill health: this is a necessary truth." In other words, philosophers assert that, among the justifications commonly accepted for departing from equal treatment of all, namely, merit, contribution or need, it is need that characterizes justice in health care (Nozick, 1972; Walzer,1983; Daniels, 1983). Conversely, they agree that allocation of medical care on the grounds of personal merit or social contribution would, on the face of it, constitute unfair or unjust distribution (Outka, 1972).

However, the problem concerns the competition of many persons with claims of equal need for a scarce resource. Here the general agreement splits into two distinct factions: one favors an approach to distribution of the scarce resource based upon the principle of social utility; the other favors an approach dominated by egalitarian principles. The egalitarian approach appears to command the widest allegiance among bioethicists: it is championed by Childress, Ramsey, Winslow, and the Artificial Heart Assessment Panel, whose arguments are accepted by many others. The utilitarian approach, which has seemed plausible to many physicians and policy makers, has found much

less favor with bioethics: it is espoused by Rescher, Basson and Fletcher, but generally disavowed by other analysts. The egalitarian approach leads its advocates to recommend some system of random selection as the only mechanism consonant with the dignity and equality of all candidates; the utilitarian approach requires explicit assessment of the qualifications of candidates, although it too may allow random selection when faced with two candidates equally in need and equally qualified.

B. EVALUATION OF OPINIONS

1. PREDOMINANCE OF THE PRINCIPLE OF SOCIAL UTILITY

The first extended discussion of this problem was by moral philosopher Nicholas Rescher (1969). His initial essay reflected the author's predilection for the principle of utility as the predominant standard for selection. That principle, as usually understood in philosophical ethics, states that "the moral end to be sought in all we do is the greatest possible balance of good over evil in the world as a whole" (Frankena, 1973). (In using the term "utilitarian", we are aware that there are many versions of this important ethical theory; we merely mean to designate a position that, in some form or another, attributes central importance to the overall good of society in determining the ethical propriety of an act or policy.)

Rescher states that any selection system must be simple, plausible, rationally defensible and fair. He then sets out criteria that he believes meet these standards. There are two sorts of criteria, those that include persons in a group "to be taken under

serious consideration as candidates for therapy (criteria of inclusion) and those which single out, within this group, the particular individuals who are to be given the therapy (criteria of selection). Criteria of inclusion are: (1) the constituency factor, i.e. the clientele of a particular institution or political entity, (2) the progress of science factor, i.e. research benefits to be gained from certain sorts of patients, and (3) the prospect of success factor, i.e. the likelihood of the therapy being effective in certain sorts of patients. Criteria of selection include: (1) relative likelihood of success, i.e. comparisons of prognosis for particular individuals, (2) life expectancy factor, i.e. the comparison of probable future chronological life of particular patients, (3) the family role factor, i.e. nature of relationship with parents, spouses, children, (4) potential future contribution, i.e. the likely pattern of future services to be rendered by the patient, adequate recovery assumed, considering his age, talent, training, and past record of performance, and (5) past services rendered, society's recognition of the service rendered to the welfare of society. Rescher justifies inclusion of the two latter criteria by stating, "society invests a scarce resource in one person as against another and is thus entitled to look to the probable prospective return on its investment. . . retrospective service is a morally necessary correlative of prospective service." (p. 616).

Rescher goes on to suggest a specific set of procedures by which these factors could be taken into account. The selection system would first apply the criteria of inclusion to create a group

substantially larger than those who actually can be accommodated. Next, criteria of selection would be applied by using a scoring procedure that would reduce the group yet more. The basis of the procedure would be a point rating that would give roughly equal weight to the medical considerations. (1 and 2) in comparison with the extramedical ones (3 and 5). Finally, out of the relatively homogeneous group remaining, a random selection by lottery would choose the actual recipients. Rescher states that the underlying ethical justification for his proposals is the utilitarian principle and its interpretation of justice. He writes:

> Is reference to all these factors indeed inevitable? The justification for taking account of the medical factors is pretty obvious. But why should the social aspect of services rendered and to be rendered be taken into account at all? The answer is that they must be taken into account not only from the medical but from the ethical point of view. . . moral philosophers of the present day are pretty well in consensus that justification of human actions is to be sought largely and primarily -- if not exclusively -- in the principles of utility and justice. But utility requires reference to services to be rendered and justice calls for a recognition of services that have been rendered (p. 616).

Basson (1979), writing ten years later, strongly endorses the utilitarian principle. Careful and comprehensive evaluation of the needs of society must be made by thoughtful persons using solid evidence. Then, selection should seek persons whose qualities make likely a contribution to those needs:

> By adopting a social value oriented approach to allocation, we create additional benefits, stemming from the contribution of those we save: the creation of those benefits increases our chance of bringing benefit to ourselves and to those for whom we care (p. 333).

2. PREDOMINANCE OF THE PRINCIPLE OF EQUALITY

The second important article to appear on this subject was by Childress (1970), who repudiates the utilitarian principles in favor of an egalitarian approach. Childress notes that the ethical question consists in the conflict of life with life for limited, but indispensible, resources. He opens his analysis by an analogy to a legal case, U.S. v Holmes, in which Holmes, a ship's officer commanding a lifeboat, ordered the crew to throw overboard fourteen men in order to keep the vessel from foundering. Holmes' criteria were "not to part man and wife and not to throw over any woman." The court convicted Holmes of unlawful homicide, the judge contending that lots should have been cast for this selection, for in such conflict situations no other procedure is "so consonant with humanity and justice." Childress admits that there are significant differences between the Holmes case and the ethical problem of selecting patients for life saving resources. In Holmes, persons were directly killed by others whose survivial was also at stake; in the latter, persons are permitted to die by others whose self interest is less manifestly involved. Still, says Childress, Holmes is instructive; the judge's preference for a lottery "puts those having equal rights on an equal footing. . . and guards against partiality and oppression" (p. 621).

Childress, like Rescher, proposes that selection should involve two steps. First, the selection of a pool of candidates who meet medical criteria for the treatment, and second, the selection of those out of this pool who will actually be recipients of the treatment that all cannot receive due to scarcity. The first step,

contends Childress, is not ethically problematic, although it should avoid very fine comparisons about the prospects of patients and keep the influence of psychological and environmental factors to a minimum. The second poses the ethical problem. At that state, some (like Rescher and Basson) have attempted to employ "social criteria" to make the selection. These involve attempts to assess the applicants' past and, more usually, future and potential contributions to society. Those who show the greater potential for social contributions should be preferred for treatment. Childress criticizes this proposal on three grounds: (1) it underestimates the difficulties of quantifying social needs, (2) it is difficult to say what future needs will be and to predict which persons will fulfill their potential in a future society, and (3) above all, it "dulls and perhaps even eliminates the sense of the person's transcendence, his dignity as a person which cannot be reduced to his past or future contribution to society" (p. 621).

Faced with the practical difficulty and the moral unsuitability of social criteria, Childress suggests that "selection by chance would come closest to embodying the moral and nonmoral values we are trying to maintain including a sense of man's dignity" (p. 621). Random selection, he contends, preserves a significant degree of personal dignity by providing equality of opportunity. Far from being non-rational or non-human, it is a technique that recognizes the equal right of all persons to be saved. In addition, a random procedure would tend to preserve the relationship between patient and physician since selection on social criteria would

introduce invidious comparisons between patients and undermine trust. Finally, Childress claims that a group of self interested persons, ignorant of their own talents and place in society, would choose for themselves and their children a random selection procedure, which alone provides equality of opportunity. In addition to these ethical arguments, random selection would have the advantage that those not selected would realize that their rejection was not due to lesser social worth but merely to the fall of the dice.

Among various forms of random selection, "first come first served" is preferable to a lottery because applicants make their claims over a period of time rather than as a group at one time. Their worry and anxiety would be reduced by knowing their fate was to be determined by chance rather than by fallible human selection. "Rejection can be accepted more easily, if equality of opportunity, fairness, and trust are preserved, and they are best preserved by selection by randomness or chance" (p. 625).

The theologian, Paul Ramsey (1970), discussed the ethics of patient selection for a scarce resource in his pioneering book, The Patient as Person. He does not refer to Childress' essay of 1967 nor to Rescher's article that appeared in the same year. Ramsey accepts the judgment of jurisprudent Paul Freund: "in the matter of choosing life or death, not involving specific wrongdoing, no one should assume the responsibility of judging comparative worthiness to live on the basis of unfocused criteria of virtue or social usefulness and either priority in time or a lottery or a mechanical selection on the basis of age should be followed" (1969, p. xii). Ramsey takes a strong

stand in favor of random selection. He does not adduce arguments in favor of his position that add to those of Childress. However, he uses vivid rhetoric to support his affirmation. He writes:

> When the ultimate of life is the value at stake and when not all lives can be saved, it can reasonably be argued that men should stand aside as far as possible from the choice of who shall live and who shall die. Men should then "play God" in the correct way: he makes his sun rise upon the good and the evil and sends rain upon the just and the unjust alike. This physicians do when in order to ensure equality of opportunity to live they devise a lottery scheme or adopt the practice of first come, first served to determine who among medically equal patients shall be admitted to a kidney dialysis program or be given an implanted vital organ. The equal right of every human being to live and not relative personal and social worth, should be the ruling principle. When not all can be saved and all need not die, this ruling priciple can be applied only or best by a random choice among equals. Random selection is preferable not simply because life is a value incommensurate with all other and so not negotiable by bargaining one man's worth against another's. It is sustained also because we have no way of knowing how really and truly to estimate a man's societal worth or his worth to others or to himself in unfocused social situations in the ordinary lives of men in their communities" (p. 256).

Ramsay would permit selection on grounds of social worth only when the life of a commuity is focused on a single goal, survival, as it is in the disasters of war or castastrophe. Then the selection by triage of those capable of saving the community is morally acceptable; in the absence of such an overriding goal, selection based on personal characteristics and social worth is immoral.

The Totally Implantable Artificial Heart Assessment Panel of the National Heart and Lung Institute (National Institute of Health, 1972) considered the selection of recipients for a costly technology.

It endorsed the egalitarian position of Childress and Ramsey. The Panel preferred decisions based on medical need as "the optimum criterion for establishing priorities." The Panel declined to lay down any set of rules that would make specific these medical criteria, although in attempting to determine the pool of candidates, it took all patients, up to age 74, who would be expected to die due to ischemic heart disease within a year. The Panel recognized that this criterion of medical need might produce a number of candidates with roughly equal need under circumstances when available resources are not sufficient to take care of all. In such circumstances, "it may be appropriate, once priorities have been established using medical criteria, to choose among candidates with roughly equivalent need on the basis of random selection. . . implemented either by lottery or by a system of first-come-first-served" (p. 148). The Panel rejected a selection process based upon estimates of "social worth", supported by the principle that "society is entitled to minimize its losses by saving those who can contribute most by rewarding past performance and, thus, encouraging future good performance by others" (p. 143). It critized this position by pointing out the lack of clarity in such terms as "high social value", and the difficulty of establishing a mechanism to make such decisions. The Panel noted that "the very essence of making decisions based on social worth runs counter to basic principles of equality in our society" (p. 147). It did not, however, expand on this claim that is open to many interpretations and qualifications.

The argument between the utilitarian and egalitarian approaches is carried on at two levels: on the level of the basic principle and on the level of practicality. At the level of basic principles, one confronts the perennial philosophical question of whether the foundation of moral judgment is social utility, viz. the achievement of the greater good for the greater number in a society, or the absolute moral claims or rights of each person to certain radical human goods, such as life and liberty. The literature on selection for scarce resources reflects this problem, but generally does not explore it at length.

Rescher's (1969) expression, "society 'invests' a scarce resource in one person as against another and is thus entitled to look to the probable prospective return on its investment", (p. 616) is an instance of the principle of social utility. It is one way of viewing the value of individual lives to the society as a whole. However much one might respect the life of an individual, the value of that life is, in the last analysis, to be viewed as a factor within the welfare of the society as a whole. Even if the most serious efforts are made to protect and enhance the value of individual lives, the design and limits of those efforts are dictated by the needs of the general good. On the level of principle, many philosophers offer many criticisms of this position. In the debate over patient selection, Childress' (1970) criticism notes, "the individual's personal and transcendent dignity, which on the utilitarian approach would be submerged in his social role and function, can be protected and witnessed to by a recognition of his equal right to be saved" (p.

623). From this viewpoint, society's "investment" is not merely the resources poured into a medical device or procedure; nor is its "return" the measurable usefulness and productivity of certain "social roles and functions." Rather, its investment is the incalculable and multiple contribution that a society makes to the very existence of each individual; its "return" is the very life of individuals, saved and fostered by multiple social interventions.

The analogy of "investment" when applied to the distribution of life saving resources is plausible but inadequate. Its inadequacy comes from the extremely narrow view of the investment and return. Its plausibility comes from the fact that significant resources are brought to bear on the development of certain interventions: knowledge, ingenuity, time, money, and materials. Even when these do not come "from the government," they draw, in a collective and cumulative way, from the store of human potential available to any society. Their devotion to one purpose subtracts them from other purposes. This holds true in public and private sectors and in various spheres, such as education, arts, recreation, and commerce. Presumably, the bending of efforts to certain tasks has some purpose, some goal. Some value to be is sought, some good is to be created. Also, those who make these efforts often do so in the hope that their children, their fellow citizens and many others unknown to them will benefit. Thus, the plausibility of the "investment" analogy lies in the recognition that out of significant efforts, significant goods should come. The analogy, however, does not aid much in discovering what good, how much good and to whom the good should flow. At best,

in the debate over life saving medical resources, it suggests that good should be "health." If the resources are antibiotics, health is freedom from infection; when the resources replace the heart, health is a revitalized cardiovascular system. But, in the utilitarian perspective, the good envisioned by the "investment theory" is not health in the abstract, nor even health as a personal attribute of individuals. It is more likely to be health insofar as health contributes to social productivity. The healthy person is the employed person or the active person contributing to, and not subtracting from, the welfare of the society. It is always this overall welfare that the utilitarian principle envisions. This apparently laudable goal is fraught with ethical perils.

C. SELECTION AND ASSESSMENT OF PERSONAL CHARACTERISTICS

These ethical perils appear when authors turn to practical levels. Those favoring the egalitarian approach are highly critical of any effort to assess the qualifications of individuals in a fair and impartial manner. Admitting that society does evaluate persons in many ways and for many purposes, they maintain that such evaluation is often inadequate and frequently biased. In the matter at hand, the provision of a life saving resource, evaluation approaches the impossible. In the words of Paul Freund (1969), "the more nearly total is the estimate to be made of an individual, and the more nearly the consequences determine life or death, the more unfit the judgment becomes for human reckoning. . . Randomness as a moral principle deserves serious study" (p. xvii). Authors critical of the utilitarian

approach note the impossibility of weighing the multiplicity of valuable human qualities in the same scale -- is the shrewd politician who maintains social peace through intricate compromises more valuable than the insightful novelist whose sharp criticism makes society uncomfortable? They call attention to the fallibility of predictions about future contributions by persons whose goals and attributes may change in a society where new needs are always emerging. They cite instances where obviously irrelevant personal characteristics tip the balance -- the choice of a church going Scout Leader over a respectable person without strong civic or religious interests. On the bases of these arguments, advocates of the egalitarian approach conclude that any system of selection that requires evaluation of personal qualifications will be flawed by fallibility, bias, ignorance and capriciousness and, thus, be unfair in its working and results. They are led to recommend various systems of random selection, such as lottery or first come, first serve. They see these systems as more consonant with fundamental human equality and as less open to the flaws of an evaluation system.

Advocates of social utility do not generally discuss the weakness of any system of assessment of personal characteristics. Rescher (1969) merely comments "the fact that the standard (of social contribution) is difficult to apply is certainly no reason for not attempting to apply it" (p. 617). Basson (1979) admits that techniques of assessment are "imperfect, but succeed better than random chance in maximizing social value of the selected candidates . . . errors are regrettable but . . . more such errors would have

occurred had we used any other allocative technique" (p. 327). On the contrary, they frequently note that the sort of assessment repudiated by egalitarians is intrinsic to evaluating medical need and medical success. An appropriate diagnosis and prognosis rests not only on physiological information, but on many psychological and social features of a particular patient. The chances for successful treatment often depend upon intellectual and emotional capability for understanding and following a regimen and upon the "network" of support on which a patient can draw for support. As advocates of the maxim that where society as a whole makes an investment, society has the right to maximum return, they count the return in terms of productive lives saved: persons restored to self support and a life of active contribution to society. Thus, the distribution of a scarce resource in which social investment has been made or by which society may gain or lose in significant ways mandates careful discrimination between persons in order to ascertain those in whom use will be "highest and best" (Rescher, 1969, p. 616). Advocates of the egalitarian approach do not deny this, but tend to see medical suitability as consisting of more objective data and, if psychological and social evaluations are involved, recommend, as does Childress (1970), that "the attempt to establish fine degress of prospective response to treatment should be avoided" (p. 622). Childress (1977) also warns that "psycho-social factors are closely related to medical acceptability but are even more susceptible to corruption by judgments of social worth" (p. 1415).

The literature that propounds the concept of a return on social investment does not address another crucial question: who should determine what counts as a suitable return on the investment? If, as these authors assert, society invests in the development of means of health care, presumably society should determine the level of return. Since society is constituted of individuals who explicitly or implicitly contribute to that investment out of their income and efforts by foregoing other sorts of benefits, it is plausible to suppose that they, as individuals, do so because they expect to enjoy that return for themselves or for their children. At least, it is plausible to suppose that persons expect to have a chance equal to others to be beneficiaries of the investment. This line of argument seems to lead to the conclusion that if the members of a society were allowed to choose a principle of selection, they would choose the egalitarian principle. As noted above, Childress alludes to such an argument. Thus, even the social investment argument seems to circle around to the egalitarian position.

Occasionally, it has been suggested that persons who are responsible for their own illness should not be the beneficiaries of scarce resources. Indeed, insurers and employers are beginning to make decisions about premiums and employment on the basis of judgments about personal responsibility for health, e.g., smokers are considered high risk. However, this claim, which has some ethical plausibility on its face, is countered by the fact that the relationship between voluntary actions and any specific illness is generally statistical. Causes of any illness are complex and interrelated. In most

conditions and certainly for those for which cardiac transplant is contemplated -- it is factually impossible to blame any specific individual. Further, even if a unique causal connection that was unique could be established, the behavior in question might not be voluntary in the sense relevant for ascribing responsibility. Thus, the suggestion that persons be selected out of a form of health care because they have brought about their condition, has carried little weight in the ethical literature (Veatch, 1980).

Therefore, at the level of general principle, all commentators affirm a strong imperative of fair and equal distribution and almost all affirm that the grounds of that distribution should be medical need. Faced with equal need and resources less than adequate to meet those needs, utilitarians advocate criteria that will promote the greater good of society and, hence, criteria calling for assessment of personal merit and contributions of candidates. Egalitarians subordinate the promotion of the greater social good in favor of respect for the equal dignity of all candidates and, thus, reject assessment of candidates in favor of random selection. In taking these positions, utilitarians seem willing to run the risks of fallibility and bias in selection and to introduce a utilitarian calculation into the patient-physician relationship. Egalitarians, on the other hand, seem to discount the relationship between medical success and psychosocial characteristics of patients. They also discount the importance of society's interest in the return on its investment in the development of a resource.

D. SELECTION AND RANDOM CHOICE

Those favoring egalitarian principles usually propose a system of random selection of patients. Even Rescher accepts such a system after a relatively homogeneous group has been created by his scoring procedure. The lottery is defended as most suitable to human dignity, as the approach least open to bias and as a palliative to the anxiety and resentment of patients. However, criticisms of the lottery have also been made. Far from seeing a human lottery as appropriate to human dignity, some authors have been repelled by the idea. The urisprudent Edmund Cahn (1955) considers "the stakes too high for gambling and the responsibilities too deep for destiny" (p. 71). Fletcher (1969) calls a lottery "literally irresponsible, a rejection of the burden, refusal to be rational" (p. 617). Even Katz and Capron (1975), who ultimately favor a lottery, are critical:

> "the lottery is more blind than fair, for an evenhanded approach is desirable only insofar as it deals with like classes of individuals" (p. 193).

Other authors note the practical problems of a lottery: it requires a group to form before lots can be drawn, a situation that is unrealistic as patients appear serially with a need for help; patients' condition can change during waiting time. Several authors (Willard, 1980; Harris, 1975) have stressed the fact that lotteries can be rigged and, in matters of such import, are likely to be. Some authors question the contention that random selection would alleviate anxiety and several authors distinguish between the "natural" sorts of random selection, such as "first-come first-served", and artifical ones, such

as lotteries; the queue is more in accord with the realities of illness and the traditions of health care, but the queue can be "jumped" (Williard, 1980; Fried, 1974). At the same time, all systems of random selection make it possible for certain socially disreputable and dangerous persons to receive the scarce gift of life (Shatin, 1966).

A nephrologist, F. B. Westervelt (1970), replied to Childress's espousal of random selection by pointing out some "operational difficulties." First, he points out that "medical suitability" is not a single stage yes-no judgment prefatory to second stage lottery selection. Medical criteria of suitability change with clinicians' experience and with forms of treatment. Also, it is impossible to exclude from medical suitability the psychological, motivational, familial, vocational and intellectual factors that "come perilously close to value judgment" (p. 216), since these are intimately related to success of treatment. Second, the "first-come first-served" form of random selection is unclear: is the "first" the patient who is first diagnosed or the first to require therapy; the one who, by virtue of conservative medical therapy, can delay entry into dialysis or the other who, neglecting the regimen of conservative therapy, needs earlier entry into a program? Third, the "photo finish" in which two equally suitable individuals compete simultaneously for a single place is exceedingly rare. Does Childress propose the tie breaking lottery or coin tossing for all candidates, even if the "adversary" is not yet visible? Finally, a patient's personality may have major impact upon the program itself, the time and morale of the

staff, and the interaction with other patients. Evaluation of this impact would be ruled out by random selection methods. Westervelt believes that, while Childress presents "a cogent, compelling theoretical argument with certain merits", triage should remain the responsibility of those answerable for the program who must avail themselves of all relevant sources of information, opinion and guidance" (p. 218).

The ethical literature does not provide detailed suggestions or analysis of the policy or systems that might implement the proposal for random selection. While it is not the business of ethicists to do so, the practicality of any approach that is ethically appropriate in principle must necessarily concern policy makers.

E. SELECTION AND MARKET ALLOCATION

One member of the Artificial Heart Assessment Panel, Professor Clark Havighurst, wrote a "Separate View". He focused on the general policy question of whether the artificial heart should not be developed. In general, he proposed an approach based on the economist's perfect world, in which all interactions are costless and all conflicts among individuals can therefore be resolved in voluntary transactions rather than by government intervention. Government would compensate for the existence of prohibitive transaction costs in the real world and would facilitate the achievement of arrangements roughly similar to those efficient ones that would be produced by cost-free bargaining among citizens having the best available information and bargaining power appropriately distributed. In this

light, the ethical imperative is to find ways of compensating the losers in any social action and preventing the gainers from enjoying windfalls at others' expense. Although Havighurst did not specifically address the ethics of selection of candidates, he criticized his colleagues' remarks on the subject as "disappointing in their superficiality" (National Institute of Health, 1972, p. 243). It can be presumed that Havighurst would prefer a method of selection that approximates the operation of the market with various adjustments to rectify gross unfairness.

Although the market model for health care has been extensively discussed in economic and policy literature, ethicists have yet to analyze in depth its implications for fair and just distribution. Almost alone among moral philosophers, Robert Nozick has advocated the free market in medical care as an ethical principle (Nozick, 1974). Most authors seem to assume, though they seldom demonstrate, that a market in which only individuals who have the resources and the desire to purchase care are able to do so, is obviously unsuitable when the commodity is essential to save and sustain a life otherwise doomed. As Outka (1974) writes, ". . .health crises are often of overriding importance when they occur. They appear therefore not satisfactorily accomodated to the context of a free marketplace where consumers may freely choose among alternative goods and services" (p. 588).

The ethical literature about the morality of a market in health care is sparse; even less is said about the market as a means of allocation of a scarce life saving resource, as Havighurst suggests. In the almost unique example of a detailed philosophical analysis of

medical costs, Menzel examines the ethical aspects of such a proposal. A competitive market would relieve government or society of the difficult task of establishing a policy about fair allocation, but it is ultimately unsatisfactory. Menzel (1982) concludes, "while competition may solve the problem by avoiding the need for the difficult to get political consensus, it generally does so at the cost of injustice to the likely ill" (p. 142). Even the policy literature, where the advantages and disadvantages of the competitive market are discussed at length, rarely approaches directly the problem of the life saving resource. One extended discussion by Katz and Capron (1975) examines the various sorts of adjustments that might ameliorate the worst effects of a competitive market in care for catastrophic diseases. However, even with adjustments, these authors are unfavorable. They write,

> Modifications in the market -- by changing what is bargained for or people's ability to bargain -- do not seem likely to solve the problems inherent in the market system. In particular, we doubt that people's willingness to pay for and undergo a lifesaving treatment corresponds exactly to the value of their lives to society and, even if it did, the market does a poor job of allowing them to express their valuation. . .the premise (that a person's wealth reflects their value to society) would be dismissed out of hand by most people today, both as a factual matter and as a deviation from our collective equality of all persons. (p. 188).

1. MIXED PRINCIPLES

Havighurst's brief discussion of selection alludes to Calebresi's thesis that, in making tragic choices, society tends to move continually from one solution to another as a means of preserving and regularly asserting its humanitarian self image; the use of social

worth criteria, (e.g., draft deferments), lotteries (e.g., Vietnam War draft) and market systems (e.g., the volunteer army) are alternatively chosen as particular ethical objections and discontent with each solution are asserted. This, says Calebresi, permits all values to be recognized in turn so that none of them is totally denied" Havighurst found this an "intriguing model for appreciating the dynamics of social response to moral dilemmas" (National Institute of Health, 1972, p. 246; Calebresi, 1978). Presumably, he would not rule out any selection procedure a priority nor select any as ethically mandatory.

Calebresi suggests that this use of various means of selecting for tragic choices will appear at successive times in the history of a nation. Winslow (1982) goes further and attempts to spell out what sorts of historical situations are likely to foster one or another mode of selection and even to justify the dominance of one principle over another.

Taking as "prismatic cases" the problem of medical triage posed by a major disaster, such as the San Francisco earthquake, and the problem of distribution of an expensive technology, such as the implantable artificial heart, Winslow analyzes the arguments and suggestions presented in the philosophical literature up to 1980. He subjects to careful analysis alternative theories that might govern an ethical selection process: the utilitarian and the egalitarian. The utilitarian approach stresses social benefits; the egalitarian, the rights of individuals. He states five principles that function within a utilitarian system: priority is given (1) to those for whom treatment has highest probability of success, (2) to the most useful

under the immediate circumstances, (3) to those who require proportionately smaller amounts of the resources, (4) to those who have the largest responsibility to dependents, and (5) to those believed to have greatest social worth. Five principles also characterize the egalitarian approach: priority given (1) to no one if not all can be saved, (2) to the medically neediest, (3) to the most helpless or generally neediest, (4) to those who arrive first, and (5) to those selected by chance.

After noting the ambiguities and practical difficulties, as well as appropriate applications of each of these principles, Winslow (1982) remarks that most proposals about selection are "mixed", but:

> these "mixtures" are generally weighted in the direction of either utility or equality. Either the prescribed approach is fundamentally utilitarian with equality on the basis of need introduced as a secondary consideration or it is fundamentally egalitarian with exceptions for utility or efficiency being made to bear the burden of proof (p. 107).

Winslow then applies philospher John Rawls' reasoning about the "original position" to the question of selection. On the basis of his conclusions from this reasoning, he proposes a "structure" of principles for a just and fair system of distribution of a scarce resource. This structure reveals how some of the various principles previously examined can be applied in different ways and with different emphasis in the two prismatic cases of major disaster and allocation of expensive technology.

Winslow (1982) analyzes the selection of patients for the artificial heart, a case that is analogous to cardiac transplantation, and concludes that:

> Rational deliberators behind the veil of ignorance would choose to allocate the kind of scarce medical resource represented by the artificial heart in accordance with a principle of fair equality of access. The contractors would not accept such utilitarian approaches as selection on the basis of general social worth. But they would incorporate in the triage process principles of efficiency that would maximize the probabilities of successful medical outcomes. Equality of access, instituted by a system of random selection, would be for those candidates known to be medically eligible at the time of triage. Medical eligibility would be interpreted generously. But minimally it would require that there be reasonably good chances for medical success without using a disproportionately large amount of the resources (p. 149).

2. SELECTION AND SUITABILITY CRITERIA

Winslow's "structure of principles" would promote "medical success". If a health care technology is to be considered "therapeutic" rather than experimental, it must be successful. In order to be successful, those patients must be selected who are most likely to be benefitted. Selection criteria can be developed that identify prospects for "highest and best use" of the resource. These criteria go beyond purely physical and physiological conditions, and encompass psychological and social situations such as "positive attitude", "supportive network", etc. These latter are included because it is believed that patients who enjoy these attributes are much more likely to respond positively to the therapy than those who do not enjoy them.

Patient selection criteria of this sort have been developed through the experience of the several centers that have performed cardiac transplants during the last decade. They usually consist of criteria revealing the need for a cardiac transplant and the

probability of successful outcome. For example, the patient must be assessed as having Class IV cardiac disability (a bed to chair existence) and no chance of being helped by medical or other forms of surgical treatment. The patient must have no contraindications to treatment, such as recent pulmonary embolus, and no other major diseases, and in addition, certain psychological characteristics are expected to improve the chances for successful outcome. The patient must have a "will to live", the strength to endure stress, and the capacity for medical compliance. Finally, certain social characteristics are also important, particularly a supportive network of family or friends and a stable environment for rehabilitation. All of these criteria are said to be indices of need for transplant and of successful outcome in terms of survival and rehabilitation.

Often such criteria for selection are lumped together as "medical suitability" criteria, that is, it is proposed that we ought to use scarce medical resources on those patients most suitable medically for the intervention, namely, those for whom the intervention is most likely to succeed. In some triage situations, such as the delivery of emergency medical treatment, one might have to make an on-the-spot determination about which of two patients in cardiac arest one is most likely to save by intervention. Without treatment, both will die; severity is equal. If one is selected; the other is then left to die. A decision is made to transplant the kidney or use the scarce drug on the patient who offers the best chances of success, given that he or she comes from a pool of comparably seriously ill patients.

Many authors have commented on the confusion inherent in speaking of "medical suitability criteria". To say that someone is "medically suitable" can refer simply to the fact that the pathophysiology of their illness has a known relationship to some therapeutic measure. Thus, a patient with gram-positive infection is medically suitable to be treated with penicillin but not with chloramphenicol. The suitability lies in the fact that penicillin is effective against such bacteria, while chloramphenicol, although effective, is much more toxic. However, beyond this limited usage, the expression becomes value laden in less obvious ways. Suitability may refer to the physicians' judgment, based on their experience, that patients of a certain sort do well under their care. Also, suitability may be heavily charged with values other than medical success. Thus, in the example above, resuscitation for cardiac arrest might be suitable for both patients in terms of the severity of their crisis. However, the fact that one patient has also just suffered extensive injury from an automobile accident and, even if resuscitated, might die in the operating room or have other lethal injuries, might lead the pressed emergency room team to prefer the middle aged person who has suffered an unexpected heart attack and is apparently otherwise healthy. This discrimination, while not invidious, clearly involves factors beyond the physiological: possibility of survival, quality of survival, and/or efficient use of resources. These judgments are assessments resting on many value presuppositions, not merely statements of fact. (Indeed, even the apparently obvious example of suitability for a certain antibiotic involves an evaluation about the

severity of its toxic effects in relation to the severity of illness to be treated.)

This ambiguity is compounded when "suitability" extends to hoped for results of complicated interventions for serious illness. The expected nature of the success of the intervention will be highly colored by values: is continued physiological life without consciousness considered a value? Is the value sought life restored to former vigor? How long a life? Is compromised living satisfactory? If so, what degree of compromise is acceptable? Also, the qualities prior to the intervention that might lead to its success are complex and uncertain. Their relation to success may be speculative or poorly understood. Presumably, a patient must have certain physiological capacities to be suitable for major surgery, e.g., a patient with severe lung disease is not a suitable candidate for open heart surgery. Beyond these more or less objective requirements, the influence of age, concomitant illnesses, intelligence, ego-strength, strong familial and personal relationships, etc. will almost always involve value judgments, often in the absence of factual information. Thus, "medical" suitability is a term that confuses rather than clarifies the discussion.

Nevertheless, all contributors to the debate over patient selection recognize that patients must be judged as suitable for the procedure and that this suitability is, at bottom, measured by some rather objective "medical" conditions. In addition certain other physical, psychological, and social conditions might be deemed relevant, to a greater or lesser degree, to the patient's potential to

undergo, survive, and benefit from the intervention. It seems reasonable to refer to this complex of factors, focused on the conditions for the "health success" of the intervention, as "suitability criteria".

Such an appeal to suitability criteria is often defended on the grounds that society ought to pursue a distributive policy that produces the best overall results. Appeal to suitability criteria maximizes expected payoff from intervention. Such criteria used over the long run lead to distributions of scarce resources that produce the greatest net benefits. Reasonable as these criteria are in terms of efficient use, they raise questions about implicit bias: do the physical, social, and psychological conditions leading to success belong primarily to certain social classes, racial groups, or to one sex rather than another? Do they introduce into the selection process a bias such that the social benefit of prolonged life of good quality will be offered only to persons drawn from certain social classes, racial groups, or to one sex rather than another? Do they introduce into the selection process a bias such that the social benefit of prolonged life of good quality will be offered only to persons drawn from certain groups or classes? Also, even apart from the invidious influence of prejudice and the unfavorable position of certain groups and classes, it is sometimes objected that these criteria are unfair to those who are "selected out." The less suitable candidate is given no chance at survival even though he or she might have had some chance at survival had he or she received the treatment. Between two persons equal in other respects but differing in likelihood of survival with

treatment -- and both certain of death without it -- the person more likely to survive ends up with the only chance of survival. The patient less likely to survive, who is only statistically less likely to survive than the other patient, ends up with no chance of survival at all. The conclusion is then drawn that fairness requires that we treat each patient "equally" and not discriminate against the less suitable patient by denying that patient his or her only chance at survival. But this conclusion does not do justice to the argument in favor of suitability criteria.

Arguments at least as compelling as arguments against the use of such criteria, can be made in favor of suitability criteria on fairness grounds. One such argument takes this form: rational individuals are deliberating about the design of a medical system that will always have some scarce resources to distribute. Prior to any actual experience of illness, no one can estimate the likelihood of ending up as the patient who is least suitable -- or most suitable. From such a perspective, it is prudent to adopt a scheme that uses suitability criteria: such a scheme maximizes the chances that each intervention will produce the greatest payoff -- a higher survival rate and thus the higher chance of survival for each selected candidate -- an outcome acceptable to self interested contractors. If a fair procedure can be described as the choice of priciples in a context in which we do not know which individual will benefit, then the prudent principle -- namely, suitability criteria (not on-the-spot randomization or lottery) -- is the fair one. In effect, the procedure for choosing lets a biological lottery operate as a randomizing factor.

To insist that we ignore the outcomes of the biological lottery and randomize outcomes once again -- in the name of fairness -- will lead to a result which is uniformly worse from a prudential perspective.

Such a double randomization could be defended in the name of fairness only if the biological lottery can be criticized itself as biased in some way. It is likely, as we noted above, that persons with certain social and racial characteristics will be more systematically excluded from the cadre of recipients. If empirical data reveal that some racial groups have a higher incidence of associated morbidity that would render them less likely to survive a cardiac transplantation, relatively more persons from that group would fail to meet suitability criteria. If empirical data show that persons living at a certain economic level are less likely to enter the medical care system at a time and place that would favor their referral for transplant, or show the social and psychological advantages that encourage survival and quality of life, relatively fewer persons of that sort would be chosen. It is demonstrable that persons are "dealt hand" in the health lottery not only because they have certain genetically determined biological characteristics, but because their lives have been affected by the social and economic conditions in which they live. These determinants are partly chosen, but are largely involuntary. Risk of being a victim of any particular disease is a complex of the natural genetic lottery, of the social lottery, of circumstances of one's birth and upbringing in a culture at a particular time and some chosen chances of a personal history. A fair procedure of selection will be one that rests as much as possible

on the natural lottery, recognizes and compensates for the influence of the social lottery and abstracts from the chances of personal history.

Another level of randomization is present in the suitability criteria for organ transplantation. Unlike dialysis, organ transplantation requires matching or organs for immunological compatability. This means that a queue is created, as first come candidates await the availability of a matched organ and some late comers are moved ahead because an organ suitable for them becomes suddenly available. This introduces a sort of randomization into the process that is not an intrinsic part of selection for hemodialysis.

Age is one suitability criterion for selection that must be most carefully scrutinized. It is common in medical care to associate the age of a patient with the appropriateness of some intervention. In many cases, this is based upon the fact that certain interventions will not be tolerated because of certain pshysiological conditions associated with age. However, it may also be based upon the judgment that the benefits of the intervention may not be commensurate with the cost or effort. At times, that benefit will be conferred upon the patient and judged incommensurate by the patient or by those responsible for the patient.

At other times, the benefit/cost assessment will have the good of society in view. Thus, age criteria can disguise underlying value judgments: is a cutoff at age 60, for example, based upon the inability of a person above that age to tolerate the treatment or upon lowered expectations of social productivity (Daniels, 1983)?

The HCFA solicitation for the present study mentions age as a "strongly adverse factor" for transplantation. This factor is stated in language that suggests age to be a contraindication in the first sense mentioned above. The reason given for not transplanting a patient over 50 is that "the individual begins to have a diminished capacity to withstand post operative complications." This may be so in general. However, patients over the age of 50 do frequently undergo major surgery. It is important to develop the empirical data that would, in fact, show the relationship between advancing age and successful outcome of cardiac transplantation. It is equally important to make explicit whether the age criteria is intended to refer to success for the recipient or for the social costs and benefits of providing expensive care to persons with limited life expectancy and productivity. The former intent clearly can be included in suitability criteria as explained above; the latter intent, although reasonable, must be thoughtfully examined.

A final argument for suitability criteria rests on the contingent fact that cardiac transplantation has been in a continual state of evolution since its introduction, particularly with regard to the use of drugs to counter rejection. Dialysis, as a technology, has been relatively stable. It is possible to suggest that transplantation remains investigative and that the selection criteria appropriate to establishment of a "record of efficacy" are suitable. Even the most severe critics of assessment, such as Sanders and Dukeminier (1968), agree that, "If a project is experimental, the use of broad discretion

in selecting candidates who can demonstrate the validity of the project is not objectionable" (p. 378).

There are two important implications. First, in recognition that certain groups will more consistently fail to meet suitability criteria, it seems fair to attempt to compensate in certain ways. Attempts at amelioration of socio-economic factors known to disadvantage certain groups can be made. Failing amelioration, targeted programs of care can be devised. More particularly, certain transplant programs might be designed with criteria that would admit the disadvantaged in hope that, by taking on the "harder" cases, methods of care might be devised to compensate for socially unfavorable correlative morbidity rates. It might be learned that, under optimum care, absence of certain suitability conditions are not, in fact, contraindications for transplant. Special programs to deal with particularly difficult social and psychological contraindications should be established. It is possible to deal administratively with some of these disadvantages and, in that way, to compensate for the "bad deal" that certain persons receive in the biological and social lottery.

A second implication of accepting suitability criteria as ethical ground of patient selection is the legal charge of discrimination. Members of the National Heart Transplant Study Team have prepared careful studies of the applicability of the principal federal legislation to patient selection criteria. Their studies suggest that suitability criteria must be properly fashioned and based

upon demonstrable evidence, to avoid running afoul of laws prohibiting discrimination on grounds of race, national origin, handicap, or sex.

F. CONCLUSIONS

Calebresi (1978) has written, "the object of public policy must be to define with respect to each tragic choice that combination of approaches which most limits tragedy and which deals with that irreducible minimum in the least offensive way" (p. 149). A decision for or against federal funding of cardiac transplantation is a tragic choice: in either case, benefits and costs will be distributed in ways that lead inevitably to suffering and death of some persons. A dramatic government policy of "giving a heart to everyone who needs it" should not be allowed to disguise the tragedy. Whether or not the government funds cardiac transplants, some persons are bound to suffer the adverse consequences. Certainly, some will die if funding is not provided; if it is, some will be "selected out" who might otherwise have obtained a heart. Some who are "beneficiaries" will receive the heart, only to be disappointed by its failure to give them life or life of quality; others who, because hearts will be available to many, may be deprived of other sorts of needed care. Resources devoted to cardiac transplant will be drawn from other programs, probably in health care, leading to the death of some who might benefit from the deprived programs. Some, who do not receive hearts, may believe they are deprived by biased criteria; others, who do, may slip under the line by mere chance. Under any sort of policy or program, tragic decisions will be made and tragic outcomes will result.

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CHAPTER 37

ETHICAL ISSUES CONCERNING DONORS, RECIPIENTS, AND PROVIDERS IN CARDIAC TRANSPLANTATION

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A. ETHICAL ISSUES CONCERNING DONORS

The era of organ transplantation brought a second ethical issue: who has the moral authority over removal of bodily organs? The most obvious answer would seem to be the possessor of those organs. The dominant ethical opinion today affirms the authority of persons over their own body. Thus, the concept of "organ donation," based on informed consent of the donor, was readily accepted for "paired organs" such as the kidney or cornea. No author has approved the concept of (or even discussed, to our knowledge) donation of a heart during the life of the donor. Cadaver "donation" has been the sole approved means of obtaining hearts. It should be noted that the concept of moral authority over one's own body is stringently limited in certain traditions. Strong ethical doctrines in Roman Catholicism and in Judaism forbid a person to mutilate his or her body. The person is steward of his or her body; dominion over the body is God's alone. Any mutilation is morally justified only if it will contribute to the well being of the person whose body is mutilated. Thus, removal of a diseased limb to save one's life is permitted (Reich, 1978, pp. 1170-1171, 1154; Jonsen, Hellegers, 1976). The advent of successful corneal transplants called for refinement of this traditional position. In both faiths, the predominant opinion at present allows that the removal of an organ for immediate and genuine benefit of another person should not be considered a reprehensible self mutilation: indeed it is an act of charity. However, this position envisages that the removal of the organ will not cause serious detriment to the donor; certainly, removal of the organ would

not be tolerated if certain to result in the donor's death. Thus, donation of one's heart while still living would be forbidden and condemned as suicide.

While Roman Catholicism and Judaism would certainly condemn a donation that would be tantamount to suicide, an argument in support of heart donation by living persons could be made under secular ethics. Contemporary ethicists do not argue strongly for the ethical impropriety of suicide. Further, a suicide that would benefit another might seem praiseworthy. In fact, several cardiac transplant centers have reported such offers. This issue does not appear to be discussed in the ethical literature. Quite possibly the arguments against such a practice would rely primarily on the inevitable presence of coercion and inducement that would undermine the presumption of free consent. In addition, one might argue that the knowledge of the donor's deliberate death could be devasting to the recipient. Even in the absence of explicit literature, therefore, there is a strong basis for opposing the concept of donation from still living persons.

The question then arises whether it is ethically necessary that a person freely donate his or her organs on the occasion of death or whether other parties, such as family or the state, may authorize the taking of organs that the deceased has not specifically donated. In general, ethicists have not argued that a voluntary donation prior to death was ethically mandatory, although some would probably maintain that an explicit refusal to allow one's organs to be removed should be respected. In the rather sparse discussion of this issue, it appears that ethicists are satisfied that next of kin can permit removal of an

organ and, in their absence, the organ could be removed. Caplan has advocated a "presumed consent" approach to organ donation, while acknowledging the inherent problems in the computer-based record keeping necessary to coordinate donors and recipients. This policy would help to alleviate the shortage of organs and "routinize the procurement. . .in a way that best protects the interests of all parties. . ." (Caplan, 1983, p. 32). The Western philosophical tradition contains nothing that would argue against the ethical propriety of a person willing body parts after death for certain uses, provided those uses were not in themselves reprehensible. At the same time, there is little in this tradition that would support the requirement that all removal of organs must be sanctioned by an explicit voluntary donation. Indeed, one of the stronger modern ethical theories, utilitarianism, could provide a plausible argument that any use of the body of a decedant that could benefit society would be mandatory, unless society's revulsion or discomfort at certain uses counterbalanced the advantages.

There is an explicit moral prohibition in Jewish religious law against mutilation of the dead body. Again, contemporary developments have refined that position and allowed it to be interpreted as permitting removal of an organ when the life of another can be saved thereby. Even then, care must be taken that contact with the dead not cause religious defilement (Rosner, 1979).

Several other religious traditions are most cautious about transplantation. Islam holds beliefs about resurrection that require bodily integrity. Buddhism also abhors mutilation of the body and

transplantation has been viewed skeptically. Nevertheless, in Islamic and Buddhist countries, donation after death has been permitted if the explicit consent of the donor has been obtained before death (Reich, 1978, pp. 891, 893, 1171, 137). The only question that deserves fuller consideration is whether organs should be removed and used for transplant against the explicit wishes of the decedant or the family. One might argue that the cadaver belongs to the state or to society. There appears to be little objection to this position in some countries: in France the law permits the removal of organs from any cadaver unless there is an explicit prior refusal by the decedant or objection from the next of kin (Raymond, 1978).

Several ethicists have argued against a routine salvaging of organs. Ramsey proposed that "the routine taking of organs would deprive individuals of the exercise of the virtue of generosity" (Ramsey, 1970, p. 210). Veatch also states that, in a "society which values personal integrity and freedom, we must be able to control our bodies not only in our lifetime but within reasonable limits after that life is gone," (Veatch, 1976, p. 268).

Muyskens takes the opposite position. He contends, against Ramsey, that routine salvaging does not deprive persons of the opportunity to excercise the virtue of generosity simply because there are many ways to demonstrate that virtue. Against Veatch, he argues that salvaging does not undermine individual autonomy because in the complex relationship between individual and collectivity, not all powers vested in the state threaten the autonomy of the individual. Muyskens takes the position that "with regard to organs such as the

kidney--given the relatively good chances of successful transplantation --we (pragmaticaly) ought to be (hence, if acting rationally would be) willing to relinguish our right to be buried intact," (Muyskens, 1978, p. 97). Since he conditions his proposal on the efficacy of renal transplantation, it is unclear what he would say about salvaging hearts for transplantation.

Muyskens' thesis implies the acceptance of the utilitarian principle that actions are ethically right if they contribute to the greater good of the greater number. Such a principle supports the beneficial use of organs that otherwise would simply corrupt. Nevertheless, the same principle might support respect for individual choice on the basis that salvaging organs without permission might have some social disutility, e.g. undermine in a progressive fashion the inviolability of the human body before death, etc. Furthermore, it could be argued that salvaging might counter the religious or moral feelings of many persons, leading to feelings of outrage and discrimination which are also social disutilities. In addition, it would also be important to acknowledge, if not the absolute authority, at least the privacy and sensitivity of the family. It does seem likely that a thoughtful philosophical consideration of this issue would result in the conclusion that, in general, social use of organs was ethical and superseded the ethical value of individual or familial rights to prohibit such use. Nevertheless, there might be important policy reasons for preferring a position that would afford certain legal protections to the refusal of individuals and families, as well as requiring permission of next of kin when available. It is

important that laws be devised that will make organs available with ease, while at the same time respecting the limitations of family and individual rights. The problems encountered in framing such a statute can be seen in the history of such an effort in Virginia (Lombardo, 1981).

Recently, a proposal has been heard to establish a market in organs for transplantation. From the earliest years of corneal and renal transplantation, indigent persons have, on rare occasions, offered to sell one of their "disposable" organs. These offers do not appear to have ever been accepted. At the same time, a market in blood has flourished alongside the voluntary donation system. Thus, society seems willing to tolerate the buying and selling of bodily parts if the parts can be readily restored. Other moral features of the market system have been ignored, although in the eyes of thoughtful commentators, they are negative enough to advise the abolition of this system (Titmuss, 1971). There has been some discussion among ethicists about the suitability of a market system. Ramsey (1970) argues against it because the market would undermine the ethical motivation of generosity, an argument brought by Titmuss against the market in blood. Ramsey recognized the inadequacy of the voluntary system of procurement and, to remedy it, proposed a trade in organs in which persons of families would freely offer organs of their deceased members and be eligible for an organ when needed.

A philosopher and a physician discuss the sale of organs and both of them find no moral objection. The philosopher, Mavrodes, sees no morally relevant difference between selling one's time and selling

one's organ and notes that in the transplant situation, the donor is the only one who does not profit financially. The physician, Frier, agrees. He notes that sale would be good for both provider and recipient and doubts that a slippery slope will be started. These viewpoints are in the minority, even in a sparse literature. A contrary position is stated by Ian Kennedy who after reviewing several arguments in favor of a market in organs, rejects them all, on the grounds that a traffic in organs would be fundamentally degrading and the profit motive would be likely to reduce care and caution in selection of suitable organs. He comments that such a debate is peculiarly American, where the idea that health care is a commodity is so easily accepted (Frier and Mavrodes, 1980; Kennedy, 1979). In the most extensive article met to analyze the ethics of a market in organs, Perry reviews the arguments for and against the two options usually discussed, namely, the donation of organs and the harvesting of organs. He concludes:

> As argued above, it would appear that any advantage enjoyed by the effective giving of organs is equally enjoyed by the harvesting of organs. Likewise, any disadvantage suffered by the harvesting of organs is suffered equally by the effective giving of organs. Moreover, the equalization of the same advantages and disadvantages appears duplicated between the two policies when monetary reimbursements added, for example, the giving of organs becomes the active selling of such while the harvesting of organs becomes the passive selling of such. Therefore, if the above is correct, the four approaches to organ acquisition appear equal with respect to those problems which affect all of the policies. There is, nevertheless, at least one major problem connected with the selling of organs which is irrelevant to the nonselling policies. The selling of cadaver or neomort organs transgresses the accepted principle that no individual is entitled to claim ownership of a dead body for commercial profit (Perry, 1980, p. 68).

Perry considers that this prohibition against the commercial use of the corpse is actually against profiting and a market could be constructed in which there would be reimbursement but not profit. To the objection that in a market for organs only the wealthy would be able to afford them, Perry responds that prices would be arranged that would not make the organs prohibitive. Thus, he can find no serious argument against a market in organs.

Perry, however, does not consider one of the more serious objections against a market. It would appear that a market would encourage desperate persons to offer organs for sale pre- or post mortem. There would be an opportunity for exploitation of the poor. This is an example of the "blocked exchanges" of which Walzer speaks: certain sorts of human exchange that might be accomplished with efficiency through a market system are not permitted by a society primarily because they are "desperate exchanges or trades of last resort. . .this is a restraint of market liberty for the sake of some communal conception of personal liberty, a reassertion at lower levels of loss of the ban on slavery" (Walzer, 1983, p. 102). There are other objections. A market system would encourage the development of a class of "middle men" and "entrepreneurs" whose practices might be less than savory: they would be modern counterparts of the 19th century graverobbers. Finally, a market might make it difficult to sustain the sort of quality control over organ accrual that is necessary for the best medical care. This is another of Titmuss'

objections to the market in blood that seems to be borne out by the safety problems of the American commercial blood system.

Caplan (1983) writes:

> Allocating life saving organs by the ability of those in need to pay what the market will bear is blatantly unfair to the poor. Nor can medicine morally allow itself to be used by those who would risk their own health out of greed, desperation or ignorance. To argue that the sale of organs is a business motivated by humanitarian concerns for the well being of those in need simply flies in the face of the fact that selling organs can only increase the cost for those who now receive them for free.

He suggests the need for legislation and social arrangements that would tip the balance in favor of donation.

The arguments against a market in organs do not rule out certain arrangements that might involve monetary considerations. Tax deductions or reduction in hospital bills might increase the incentive to donate. The idea of organized giving to charity based on similar incentives was probably frowned upon in the earlier years of this century by those accustomed to giving solely for the sake of charity, unmotivated by anything but generosity.

It must be kept in mind, of course, that the discussion of a market in organs has been framed in the context of sales by individuals of one of their own matched organs-primarily, a kidney. Cardiac transplantation poses the rather unusual problem of an individual offering for sale an organ whose loss would cost his or her own life or an organ that could be taken after death with payment to relatives. The complications of such a market have not been explored.

B. ETHICAL ISSUES CONCERNING THE RECIPIENT

Certain ethical issues concerning the recipient have been treated in the two previous chapters. In particular, those essays reported the positions on whether an individual can be said to have a moral right to an organ transplant. In general, the survey of the literature reveals that there is no strong sense in which a person can be said to have such a right. At the same time, authors agree that principles of fairness should be observed in selection of patients. However, several ethical issues of some importance require explicit review: informed consent, termination of life, and quality of life. These three issues have been extensively treated in the ethical literature in a general way and, to some extent, with particular reference to transplantation.

1. INFORMED CONSENT

There is universal agreement that competent patients must be accorded respect by providers of medical care to them and that respect entails seeking their consent after informing them about the nature of their disease and about the risks and benefits of possible treatment and treatment alternatives (President's Commission, 1982). Their informed refusal of treatment should be respected. While all ethicists affirm this doctrine of informed consent, they discuss at length its limits, exceptions and difficulties. The consent of a potential transplant recipient should also be sought after the presentation of adequate information on which the patient can base a reasonable decision.

All of these moral requirements must be scruplously observed in cardiac transplantation. Yet certain features of this medical technology call for special attention to the problem of informed consent. First, as the President's Commission points out, "informed consent" should really be considered a form of education rather than the limited interaction of giving information and asking consent. The patient should have the opportunity to develop a genuine understanding of the medical situation, the nature and effects of the treatment and its impact on survival and quality of life. Consent should flow out of this understanding. Such an understanding will be colored by attitudes and emotions, some of which will be unrealistic. Thus, sensitive and supportive counselling should precede and follow the decision to accept a transplant. Yet, patients sometimes will have little opportunity for such educational counselling and programs will have little skill in providing it. Given the moral importance of this aspect of transplantation, it is questionable whether programs that perform surgery but cannot provide suitable counselling and education for patients and families should be supported.

Second, candidates for cardiac transplant might be considered among the particularly vulnerable patients for whom voluntary, informed consent is particularly difficult. They face imminent death on the one hand or, on the other, high risk surgery and the real possibility of compromised quality of life. Even when this is clearly explained and understood, major coercive forces may press upon the patient's decisions. A chance for life rather than death is a compelling motive. Family may exert subtle pressure to go through

with the surgery. The drama itself may compel acceptance. A community or group of friends may have provided emotional and financial support and cannot be disappointed. The sudden availability of a suitable organ may rush the still hesitant patient. The very acceptance into a program as a suitable candidate may strongly influence the decision to stay. All these and other social and emotional forces on voluntary consent must be recognized and, if they are negative, ameliorated to the extent possible.

Third, although at present children are not commonly recipients of cardiac transplants (although they are of renal transplants), they are likely to be in the future. Depending upon age, children and adolescents will have greater or lesser capability for granting consent. For the young child, consent may be impossible; for the adolescent, consent may be possible but compromised in many ways. A policy regarding transplantation for minors should be contemplated now rather than at the point of its feasibility. Indeed, its feasibility will depend on the experimental lowering of the age limits for experimental procedures; this lowering itself raises the ethical problem of consent for experimental procedures.

Finally, informed consent for therapy and informed consent to experimental or research procedures have been deemed to be different in several respects. There are differences in the autonomy of the patient as compared to that of the research subject, in the relationship of physician and patient as compared to that of investigator and subject, in the rigor of protocol as compared to the adaptability of diagnostic and therapeutic manners (Levin, 1983). It

is important that these differences be clearly understood in the area of cardiac transplantation.

2. QUALITY OF LIFE

It is often said that the quality of life of transplant patients is an ethical issue. It is unclear what is meant by such a statement. Quality of life is a vague phrase. It can be used to designate the satisfaction of a person with his or her own life or the evaluation of certain states or experiences by a party other than the one who has them. Transplant patients present themselves to physicians precisely because of a personal judgment that their life is not at all satisfactory to them: they are severely limited in physical activities, suffer from shortness of breath, etc. They feel themselves to be, and objectively are, near death. They seek a better quality of life and are advised by physicians that they have a chance for better quality of life through transplantation. Whether better quality, in terms of improved physical status and improved chances for life, can be provided is an empirical matter. The extent to which improvements of certain sorts can be expected and the probability of their being effected must be honestly communicated to the patients. Their understanding and acceptance of this information is a matter of their informed consent. Similarly, the risks of failure, of disappointment or of a worsened condition must also be explained and accepted or rejected by the patient. In this sense, quality of life is not so much an ethical problem in itself as it is an aspect of the ethical problem of informed consent.

The second use of "quality of life" raises a unique problem. The problem was referred to in Chapters 32 and 36. When providers select patients for transplant they may employ certain data about personal life, behavior, and familial and social environment in order to assess the patient's suitability. This sort of data and its evaluation might be summed up as quality of life. Similarly, such judgments might be used in formulating policy about allocation of resources. Classes of persons whose life was of certain quality or persons whose life was not expected to attain certain quality as the result of therapy would be excluded from consideration as candidates for selection.

Here the ethical problem seems to be the danger of prejudicial judgment, of employing irrelevant criteria to distribute benefits within the society. Ethics can do little more than warn against this danger and attempt to provide some insight into which criteria are relevant or irrelevant for certain sorts of distributions. These points have been made at length in the Update on Selection of Patients. Law and policy bear the burden of devising remedies and protection against such discriminations.

3. TERMINATION OF LIFE

The advent of life sustaining technologies has created agonizing problems about the appropriate time to cease to use those technologies and to allow death. Those life sustaining technologies that depend on mechanical devices, such as respirators, dialysis and the artificial implantable heart, pose the problem as one of "turning off" or "pulling the plug." Within the vast ethical literature on

this matter, strong agreement exists that certain conditions do justify the withdrawal of these technologies resulting in the death of the patient. One of these conditions, indeed perhaps the most prominent, is the patient's own competent refusal of further care. Very few ethicists deny that this is permissible; most wish to distinguish such a refusal from suicide in morally significant ways. Again, the orthodox Jewish tradition would deny to persons the moral right to terminate their lives in this manner: God requires that all means to preserve life be used until the last breath. The Roman Catholic tradition has always permitted a refusal of "extraordinary means" even when refusal would lead to death: this was not considered suicide (Kelly, 1957; McCartney, 1980).

When the life sustaining therapy involves the transplantation of a natural organ that then takes up the function of the removed organ, the question is not one of "turning off." As long as the transplanted organ continues to function, the patient will continue to live, absent other lethal conditions. However, there are means of reducing the efficacy of the organ and even causing its failure. Most obvious of these is the patient's refusal to comply with the immuno-suppressive regimen and allowing his or her body to reject the transplant. Some patients unhappy with the quality of life they have after transplant may choose to do this. Should such an action be considered as ethically distinct from suicide? While the procedure of transplantion might be considered extraordinary, is the transplanted heart or kidney an "extraordinary means" of sustaining life? This

question does not appear to have even been discussed in the ethical literature.

The problem does not, however, seem difficult. For the many ethicists who find strong ethical arguments to justify "rational suicide," the decision to no longer live with the quality of life sustained by a transplanted heart would seem to be morally acceptable. To those who require a distinction between suicide and refusal of extraordinary treatment, it is the burden of life sustained by the treatment (in this case the immunosuppressive regimen) that renders the treatment extraordinary. If a diabetic facing death by cancer can discontinue insulin as extraordinary, it seems reasonable to approve of discontinuing prednisone. Finally, those who allow no distinction between suicide and refusal of treatment would not approve of any decision to terminate life sustaining treatment (Kuhse, 1981; Rachels, 1983; Kelly, 1957).

C. ETHICAL ISSUES CONCERNING THE PROVIDER

Almost no discussion of ethical issues concerning the providers of transplantation appears in the ethical literature with the exception of some criticism of providers of therapies for end-stage renal disease. This critique, which has not been carefully analyzed by ethicists, reflects the impression that the availability of federal funds to pay for these therapies has led some practitioners to be entrepreneurs for profit and to provide these treatments even when they were not medically indicated. The accused answer that they do not, in fact, exploit the federal subsidy, that they maintain strict

medical criteria and that their for-profit status actually keeps the costs of care lower than it would be otherwise. They presume that they have the ethical and legal right to provide care in this manner (Relman, 1980; Lowrie, Hampters, 1981). This particular discussion raises the deeper questions about whether physicians have a moral right to control health care resources in some significant way or whether and to what extent they have social obligations that might limit any such right.

The ethical responsibilities of providers of health care have been extensively discussed in the literature. However, these discussions almost exclusively concern the moral obligations arising in the patient-physician relationship. Very little has been written about the social obligations of providers of health care (Jonsen and Jameton, 1977; Daniels, 1981). Also, the rights of providers have hardly been discussed at all. An article by Sade (1971), accorded to physicians the right to dispose of the medical skills they have attained without interference from others. This property right in one's own talents and educated skills is a corollary of the fundamental right to life. Sade's article was oft noted, but more often dismissed by ethicists than analyzed (Jonsen, 1978; McCullough, 1979). Although ethically unsophisticated, Sade's thesis can be seen as an expression of the libertarian point of view propounded by Nozick. Individual property rights, says Nozick, are immune to being overidden in the name of social goals (Nozick, 1974). Basing his argument on the Kantian doctrine that persons must be respected as ends, he argues that an individual has the moral right to advance his

interests by employing his natural talents and assets and cannot morally be limited by any social constraints unless he consents to them.

Sade's position and its more philosophical justification by Nozick reflect the cultural, social and financial status of American medicine. In the course of its history, the medical profession in the United States has achieved that form of monopolistic control over health care that entails great freedom for individual physicians to determine how, when, and where they shall use their skills (Starr, 1982). They have been able to advance their interests effectively. Attempts to control and limit this large autonomy have been, until recently, defeated or, at least, controlled by organized medicine. In light of this history, these vested interests have often been seen as "rights" and threats to them as infringements of rights. Principle VI of the Principles of Medical Ethics of the American Medical Association, revised in 1981, strongly affirm this right: "A physician shall in the provision of appropriate patient care, except in emergecies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical services" (AMA Judicial Council, 1981, p. ix).

It is this conception of the "rights" of physicians to control the resources of health care that gives rise to the certain questions about providers of cardiac transplantation. Given the relative scarcity and high cost of this procedure, do physicians and institutions have the right to exercise significant control over its availability? Do individual physicians have the moral right to offer

cardiac transplantation? Is it right to impose various sorts of regulatory limitation on the liberty of providers or to restrict their pursuit of their interests in the name of a fair and just allocation of this resource? This section will discuss the nature of the physicians's right to practice medicine and to choose patients. As we mentioned, despite the extensive discussion of these questions in the policy literature, the ethical literature is not ample. We can, at best, suggest the general tenor of that literature.

1. COMPETENT PRACTICE

It might be said that a provider has the right to act in a free and unimpeded way to provide medical benefits to a person who seeks them only if several conditions are present. First the provider must possess competence. In the general sense, the provider must have that knowledge and skill requisite to effect the benefit promised by his or her attendance on the patient. Otherwise, the provider would be guilty of deception and would be the negligent agent of any harms that might come to the patient as a result of attendance. There are many difficulties in further specifying the ethical duty of competence: in what does competence consist, what are the standards of competence, who assesses competence, how is competence attained, maintained, and enforced, are there degrees of competence, etc. Assuming these difficulties can be managed in some reasonable, even if insufficient manner, it can be asserted that a provider has an ethical right to practice the skill he or she has acquired and desires to utilize for personal benefit as well as benefit of others.

Second, the competent practitioner must also profess the intention "to benefit and do no harm" to those who come for help. It is the nature of a profession to make such a promise in a collective fashion by a statement of "ethics" and by a system of self regulation. The profession is granted certain privileges in return for this "promise" to benefit individuals and society. There are, however, few objective tests of this intent: it is an implicit declaration by individuals. The legal authorization to practice medicine rests on these two conditions and the license granting the right to practice requires proof of competence.

When new technologies appear in medical care, competence requires that providers learn how to employ them skillfully. Complex technologies demand considerable formal training. If the ethical and legal right to practice is to be maintained, all measures judged necessary to attain competence in the new technology must be followed by the practitioner. Thus, a cardiac surgeon may have general competence, but have no specific knowledge or skill in the particular activities relating to cardiac transplantation. It would be ethically absurd to claim that such a person had a moral right to perform cardiac transplantation. However, ethics can say nothing about how such competence is to be attained, judged and enforced.

2. CHOICE OF PATIENTS

It is often asserted that a physician has the right to choose whom he or she will serve. Principle VI of the Principles of Ethics of the American Medical Association explicitly mentions this right (AMA Judicial Council, 1981). This affirmation can probably be

sustained by ethical argument, but with certain limitations. It is generally agreed that a physician cannot ignore a person in medical emergency. However, there is no agreement in the literature that a physician's right to choose is limited by social needs: those ethicists who affirm a strong right to health care so limit physician choice of patients; those who are more skeptical about such a right provide wider scope for physician choice. In the matter of medical technologies in general, no peculiar ethical problem appears until it is perceived that the employment of that technology creates a social problem by misallocation of resources. At this point, it may become clear that some social values have priority over the value of individual choice and care that usually obtains. If cardiac transplantation is seen in this light, then the policies for allocation of these resources and for selection of patients would supersede the right of physicians to choose their own patients. Ethics cannot say, however, how such an ethical priority can be reflected in social policy. It can only assert that if a particular technology must be allocated in view of social values, there is an ethical obligation to adhere to the selection criteria that will promote those goods.

The most extensive discussion of the limitations on providers' rights or autonomy is found in Daniels' book Just Health Care. He frames these limitations in terms of the requirement of justice that priority be given to meeting some needs when not all needs can be met. Daniels summarizes the implications of his thesis for the autonomy of providers:

> I have argued that the kinds of constraints on physician autonomy forced on us by requirements of justice do not involve the violation of any fundamental or basic liberties, nor do they necessarily do injustice to physicians. The restrictions on traditional autonomy that affect access to care need only involve establishing constraints on choice on a par with those faced by many other classes of professionals and workers. The restrictions on autonomy in treatment decisions imposed by just resource allocation policies also violate no basic liberty. Moreover, the restrictions need not interfere with valuable features of the doctor/patient relationship, provided there is a division of responsibility between society and the physician, so that rationing decisions are not the responsibility of the physician (Daniels, in manuscript, p. 227).

Is is also commonly assumed that the physician has the right to practice as an individual: if competence is demonstrated in some specialty, the physician may establish a private practice and solicit patients. However, the fact that this practice is customary and legally sanctioned does not ground the practice in any moral right. Competence is not only a personal quality, but also the ability to function in certain relationships. For example, it is now evident that hospitals that perform only a few surgeries of a certain sort have less success than institutions that perform larger numbers of those procedures. Thus, even a surgeon who has excellent skills will likely be less successful working alone than with competent colleagues who have frequent experience. It is suggested here that the right to practice competently may be limited by the responsibility to practice in certain sorts of situations in which the probabilities of success are better. When the success is not only the cure of an individual, but a social good, the designation of place and situation of practice might be left to the government or to some independently designated

agency or authority. Only certain institutions might be licensed as centers for the procedure in question. Only certain individuals or institutions judged to be superior might be certified for reimbursement for procedures. Again, it is a matter of policy rather than ethics to determine whether such a plan could be devised and carried out.

Although the ethical literature on these questions is rather sparse, certain directions are visible, not only in the explicit discussions of these questions, but in the more general discussions about the roles and functions of providers of health care. Those directions can be summarized in the words of Daniels, "Primary obligations in the distribution of health care are the social rather than the individual or professional obligations of physicians" (p. 197). When ethicists turn from the duties of physicians to their individual patients to the questions of justice raised by the allocation of resources, they affirm, with almost one voice, the social nature of these obligations. With the notable exception of Nozick, whose theories of justice turn on a libertarian doctrine, almost every ethicist affirms that providers' claims of individual rights and autonomy are subordinate to the needs of society for health care. Veatch (1979) explains this in terms of a "triple social contract," the first between society and its individuals, the second between the profession and society and the third between patients and physicians. In these terms, it can be said that the first social contract aims at a just allocation of health resources and fair access to them, while the second allocates rights and duties among all who would provide health care and all who will be recipients of care. The

terms of the third contract must respect those of the first two. In light of this thesis, claims of individuals autonomy that violate the just conditions of distribution envisioned in the first two contracts deserve no moral credence. In a careful analysis of the problem of constraints on individual liberty of patients and physicians occasioned by various health policies, Brock (1983) reaches the same conclusion:

> Whatever limits on the use of possibly beneficial health care are reasonable limits due to cost are also reasonable limits on the liberty of physicians to do all that is medically possible for their patients there is no substantial moral liberty argument to set against moral claims to remove inequities in access to health care. (p. 256, 259).

Constraints on the autonomy of physicians to practice, to select patients or to establish practices of their own choosing can, then, be justified. Obviously, these constraints, as Daniels has observed, must not violate fundamental human rights: they must be similar to those constraints justly imposed upon all other participants in the society. Thus, constraints imposed by license, by certain forms of social and peer review, and by reimbursement policies can be devised. As in all areas of social policy, it is difficult to devise policies that are fair in all respects to those who are burdened by them. At the same time, ethics is not required to state the exact stipulation of social policy, but merely to offer the moral arguments that can justify their existence and the general conditions of fairness to which they must conform.

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CHAPTER 38

ETHICAL ISSUES IN MACROALLOCATION OF CARDIAC TRANSPLANT

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A. THE RIGHT TO HEALTH CARE

The HCFA Workscope for the Ethical Considerations asks "does an individual have a right to cardiac transplantation?" A more general question, "does an individual have a right to health care?" has been asked in recent years within the context of concern over the inadequacy and maldistribution health care in certain countries (Anderson, 1972; Starr, 1982). Efforts to improve access to medical and health care have often assumed that there is such a right and have employed it as a motto. The use of the language of rights, although it mayto signal inequities and encourage remedies for them, has certain limitations. These have been pointed out by philosophers (Feinberg 1976; Daniels 1984). The President's Commission for the Study of Ethical Problems in Medicine, conscious of those limitations, "chose not to develop the case for equitable access through the assertion of a right to health care." (President's Commission, p. 32)

The limitations of the concept of rights in the area of health care can be briefly stated. First, the concept of rights became philosophically prominent during the 17th and 18th centuries. In the intellectual climate of that time, philosophers such as Locke and Rousseau proposed that certain spheres of personal activity should be free from interference by monarch, state, or society. Thus, the concept of rights served to assert an independence that should not be violated. The right to life or property posited a claim of individual inviolability against deprivation of life and property without due process. These "negative" rights are stated in the American Bill of Rights. Later this notion was transformed into the more positive

claim that society or the state ought to privide or assure that certain benefits came to individuals. Thus, the right to a just wage or to a job were asserted. This translation from negative to positive rights has been somewhat clumsy. The neagtive right states that each person has the duty to refrain from interfering with others' lives and pursuit of business as long as these do not cause harm. The positive right does not clearly indicate which others have a duty to provide the benefit and to what extent such a purpported duty might prevail over their own well being.

Another disadvantage of rights language is that assertion of a right has an absolute ring to it; there is an intent to exclude cost-benefit analysis. A right to a fair trial or to religious belief is not to be weighed against the disadvantages to others of one's having that right. The claim that one has a "right" is a claim that, as Dworkin has said, "trumps" other claims based on practicality, social utility, efficiency or convenience (Dworkin 1977). While rights may have certain limitations (e.g., the right to free speech does not allow one to cry "fire" in a crowded theater), the limits are assumed to be very broad. Put most generally, they are constitutional by the equal rights of others. This presumption of absoluteness gives the concept of rights limited usefulness when the issue is how to distribute scarce social goods.

The idea of a right to health care evolved in somewhat the same way as the general notion of rights. Beginning with the claim that citizens should be protected by public health measures, from infectious disease and the hazards of a polluted environment, the idea was

gradually transformed into a claim that all individuals should have access to medical care. (Chapman 1971)

While society's obligation to establish public health protections to the extent possible is clear, it is less clear that society is obliged to provide medical care. How does medical care differ from other basic needs, such as food and housing? Measures of protection from health hazards, such as quarantine or regulations for clean water, are general; needs for medical care are specific and individual. To what sorts of care and to how much of it do individuals have rights?

The concept of rights, as traditionally understood, involves correlative duties. If a right can be established on one side, a corresponding duty is established on the other. Negative rights impose duties to refrain from acting in ways that infringe upon those rights; positive rights impose duties to act, and to perform certain actions. Thus, if an individual has a right to health care, someone has the duty to provide it. While it can be said that society has such a duty, health care is carried out by individual professionals. Do professionals as individuals or as a class have an obligation to provide care to other individuals? If they do, to whom and under what conditions? Health care costs money. Who is obliged to pay: those who need care, those who may need care, or all citizens regardless of their need? How much of the public dollar should go to this social good rather than another? Green states the issue clearly: "...a right of access to health care and a corresponding social obligation to

provide health services involve labor and resources in a way that protection of the basic civil liberties do not" (Green 1983, p. 374).

McCullough summarizes the discussion about rights to health care:

> The emphasis in discussion about rights to health care is two-fold. Some challenge directly whether such a right exists at all, arguing that it does not because it is in contradiction to the basic rights of medical practitioners. Others grant that there is a right to health care and focus on the scope of that right. A consensus seems to have emerged that the right is quite limited, securing access only to a decent, fair, minimum level of health care. A sub-set of this school holds that health care as a right must be understood in institutional contexts. That is, abstract claims to basic rights will not do. Whatever rights one has, one comes to possess in virtue of being within an institutional setting and only in this way. Thus, one possesses the right to health care insofar as institutions confer such a right (McCullough, 1981, p. 53).

Jonsen attempts to define "right to health care" in a way that takes into account the limited notion of such a right. If the language of rights is used at all, it should be clear that:

> The right to health or medical care is a moral, general, and conditional right. It is moral because it rests upon the assertion that personal autonomy and the conditions for its security and enhancement should be respected. It is general because it does not arise from a particular transaction or special relationship but is prior to these and lends them their moral quality. It is conditional because its implementation in social institutions depends upon the existing material resources, and upon the continuing reassessment of the effectiveness of medical interventions (Jonsen 1978, p. 631).

Given so many conditions and limitations, the concept of a right loses moral strength and clarity. In particular, it casts doubt on the moral power of an individual person's claim to one or another

service that he or she desires or even needs. The morality of a demand for drugs or surgery is clearly different from that of a demand to be allowed to live free of other's interference upon life and liberty.

In light of these problems, the President's Commission states its reason for avoiding the concept of the right to health care:

> As long as the debate over the ethical assessment of patterns of access to health care is carried on simply by the assertion and refutation of a 'right to health care,' the debate will be incapable of guiding policy. At the very least, the nature of right must be made clear and competing accounts of it compared and evaluated. Moreover, if claims of rights are to guide policy they must be supported by sound ethical reasoning and the connections between various rights must be systematicaly developed, especially where rights are in conflict with one another. At present, however, there is a good deal of dispute among competing theories of rights with most theories being so abstract and inadequately developed that their implications for health care are not obvious (President's Commission 1983, p. 34-35).

B. JUSTICE AND HEALTH CARE

1. THE CONCEPT OF JUSTICE

Most philosophers who have discussed the concept of a right to health care, have, as we noted above, been critical of its usefulness in clarifying problems of allocation of health care services. Some have rejected it totally; others have accepted it with certain qualifications. Those who accept it often note that, as a moral notion, it fits within a more comprehensive moral theory about justice. It is such a theory that would provide the "sound ethical reasoning and connections between various rights" of which the President's Commission speaks in the above quotation. Buchanan writes

"even if we can show what makes health care, or certain kinds of health care, morally important, this will not in itself show a right to health care, unless the appropriate connection with priciples of justice can be made" (Buchanan 1983, p. 209). The conceptual relationships between the notion of rights and principles of justice are complex (Golding 1981). We will not pursue the details of these relationships but instead will turn to the principles of justice and their relevance to the allocation of health care resources. Let it be noted as we proceed, that the term "right" is commonly used by philosophers to describe the conclusion of an argument showing that one person or a group of persons have a claim in justice or fairness. In this sense, the various "rights" to health or medical care are not the negative rights criticized above but the positive rights that flow from a theory of justice.

Justice has been discussed by moral philosophers since Plato and Aristotle. The central principle of justice is "treat similar cases similarly". The problem of justice consists in determining what consitutes the similarity of cases and how the factual differences between cases are morally relevant in justifying different treatment. In the sphere of justice that comprises the allocation of benefits and burdens in a society, the question is, are there morally significant grounds on which various advantages or disadvantages are distributed differently to different parties or groups? Are certain forms of distribution fair and others unfair? The goods of society can be power, honor, wealth, access to positions, or, in the case under present consideration, health care resources.

The formal and general principles of distributive justice are in need of interpretation. This is the task of a theory of justice. In contemporary moral philosophy, several theories of justice vie for attention. Although complex, these theories can be summed up as utilitarian, contractarian and libertarian (Buchanan, in Shelp 1981). Again, we will not detail the differences between these theories for this paper; we merely point out that these theories, as well as variations of them, are incorporated in the philosophers' opinions about justice and health care. All authors whose opinions we report reject the libertarian theory, which denies governmental obligations to provide support for health care and advocates an open market for health care (Wikler 1983). The other two theories, despite their different approaches to the problem of justice, come to similar conclusions about the issue under discussion, namely, the allocation of an expensive medical resource. We will relate the positions of the principal authors and then state how these positions concur with regard to the justice of providing or not providing public subsidy for cardiac transplantation.

2. JUSTICE

Ethicists generally agree that the distribution of health care poses problems that pertain to that part of moral philosophy traditionally called Theory of Justice. In 1972, Jonsen and Hellegers wrote "Many of the moral problems of medicine appear to be problems of justice ... yet the theories of justice long familiar to ethics have not been mined for their relevance to the moral problems of medicine ... the problem of access to medical care is the most obvious field

for the application of the concept of justice (Jonsen, Hellegers 1973, p. 17). Although Ramsey had called the problem of justice in medical care "almost, if not altogether incorrigible to moral reasoning", (Ramsey, 1970, p. 240) ethicists have attempted to mine the theory of justice. The more prominent efforts will be summarized here and their relevance to the problem of allocation of cardiac transplantation suggested.

Four authors attempt to delineate the specific application of the concepts of justice to health care: Outka, Veatch, Green, and Daniels. Each emphasizes a different viewpoint and uses a different approach yet all reach similar conclusions. The President's Commission for the Study of Ethical Problems in Medicine, in its report on Securing Access to Health Care, benefits from the contributions of these ethicists and, in their light, develops its own position (Wikler 1983). In the following section, each position will be summarized and certain general conclusions about transplantation will be drawn.

Outka was the first to sketch the relevance of the concept of justice to health care. He reviews the "standard conceptions of social justice":

1) To each according to his merit or desert.

2) To each according to his societal contributions.

3) To each according to is contribution in satisfying whatever is freely deserved in the open marketplace of supply and demand.

4) To each according to is needs.

5) Similar treatment for similar cases (Outka 1972, p. 81).

He argues that the distinctive features of the crisis of health render the first three of these conceptions irrelevant as principles of distribution of health care. The unpredictability of health crises and their devasting effect on personal welfare create inequalities for which individuals are not responsible. Justice seeks to remedy such inequalities to the extent possible. Thus, distribution of health care on the basis of need for such care is the most relevant application of the concept of justice to health care. All persons should have equal access to care commensurate to their need for it.

The fifth principle of justice, "similar treatment for similar cases" is also relevant. The goal of equal access based on need may collide "with the realities of finite medical resources and need, that prove to be insatiable" (p. 92). The formula of similar treatment for similar cases can then guide distribution. It may allow "no positive treatment whatever" and thus justify exclusion of entire classes of cases from a priority list. It seems more just to discriminate by classes of illness rather than by ability to pay or geographical location, etc. Outka says by way of example, "all persons with a certain rare, non communicable disease would not receive priority, let us say, where the costs were inordinate, the prospects for rehabilitation remote and for the sake of equalized benefits to many more" (p. 92).

Veatch also examines several formulae that might conceivably be offered as principles of justice for health care.

1) Justice requires that everyone get the resources needed to be healthy.

2) Justice requires that everyone get equal health care resources.

3) Justice requires that everyone have access to any equal maximum of health care.

He rejects these formulae as incoherent. He then examines several competing theories of justice: utilitarian, contractarian and egalitarian. Criticizing the first two, he argues for the third, expressed in the formula, "everyone has a claim to the amount of health care needed to provide a level of health equal to other persons' health" (Veatch 1976, p. 133).

Veatch explains that "those whose health is the worst are entitled to enough health care to get them as healthy as others. We would target our efforts on the sickest" (p. 133). Recognizing that many claims of need can be made on scarce resources, Veatch states that the neediest have a just claim only if something fruitful can come from the resource commitment. Thus, the formula is modified to "everyone has a claim to health care needed to provide an opportunity for a level of health equal, as far as possible, to other persons' health" (p. 134).

When the question is raised whether certain diseases have priority in claims on resources, Veatch states that priority should be given to caring for those that "constitute the greatest assault on one's health - however that may be defined" (p. 141). He then notes that a certain disease that constitutes such an assault may be treatable, but at a cost that would consume resources capable of

treating many more people although they are less sick. He admits that efficiency and aggregate utility might be relevant to a judgement about the moral rightness of a certain distribution, but do not count in favor of the justice of that distribution. Thus, on grounds of justice alone, all treatable assaults on health deserve treatment. Still, given scarcity of resources, a restricted distribution might be morally right. Veatch has expanded, but not substantially modified his 1976 position in his recent book, A Theory of Medical Ethics (Veatch 1981).

Green endeavors to apply the most renowned contemporary theory of justice, that of John Rawls, to allocation of health resources. He notes that health can be a "primary good", that is, a good that all rational and self interested persons would want, whatever else they may also want. Such persons, in the hypothetical "original position" of choosing the rules they would live by under conditions of ignorance about what position they would occupy in real life, would opt for a principle of equal access. "Each member of society, whatever position or background, would be guaranteed on equal right to the most extensive health services the society allows" (Green 1976, p. 117).

Green does not explain further how resource allocation would be carried out within the health care system. It could be "on the basis of need or whatever other principles impartial agents consider appropriate" (p. 118). These agents certainly would not consider income based or geographically based distribution principles appropriate.

Green takes up the question of relating health care expenditures to expenditures for other social goods. Since health is desired because it provides the opportunity to pursue other goods, rational contractors would not provide health care at the expense of exhausting other resources. Although the logic of contract reasoning does not produce an unequivocal repudiation of medical procedures so costly as to reduce society to a subsistence level, common sense supports the idea that multiple opportunities for exercise of human capacities should not be jeopardized by the excessive costs of health care. After all, isn't the purpose of maintaining health to maintain the ability to pursue these opportunities? Where would rational contractors draw the line? Green suggests a test: "would those who entered the social contract" regret the social decision that rendered therapy for their condition unavailable, "if they fell ill?" (p. 121). He does not spell out the implications of his question.

In a later article, Green repeats his argument in favor of publicly funded system of care "approaching the ideal of equal access to the highest levels of care available". Yet he acknowledges that even this standard allows "reasonable trade-offs". Medical efforts may sometimes be limited when they do not promise substantial relief from the array of evils assciated with ill health. A social decision to provide only palliative care for the victims of esophageal cancer can be made on health care grounds alone because of the very poor prognosis...a social decision to deemphasize one form of life-saving "rescue" may be morally acceptable within the understanding of

priorities when this decision is needed to facilitate other therapies that more efficiently prevent pain, suffering or death (Green 1983, p. 378).

Childress takes up two questions, what quantity of resources should be put into health care and into other social goods such as education, defense, eliminating poverty, and improving the environment? Within the area of health care, how should resources be allocated among preventative, rescue, and crisis medicine? He answers the first question summarily by stating that resources should be invested sufficient to provide a decent minimum level of health and medical care to all citizens. In this opinion, he agrees with many other commentators. He approaches the second question at greater length. He argues that while concentration on prevention might be more effective and efficient in terms of reduction of morbidity and mortality (although this is not yet proven), other values are also deserve consideration.

Four values are particularly relevant: the symbolic value of rescue efforts, the duty of compensatory justice, the principle of equal access, and the principle of liberty. Childress considers each of these to important, but no one of them is conclusive in making allocation decisions. The symbolic value of rescue does reveal something about the character of a nation and of its people: the readiness to expend resources to save endangered life; however, as a basis for allocation, "it encounters certain difficulties". To withdraw from budgets for prevention, which in the long run might save more lives, in order to invest in crisis and rescue, is "an odd way to

symbolize our concern for human life." Similarly, those who have been harmed by society (e.g., those whose diseases result from society's carelessness) deserve to be compensated, but certain factual issues, such as causation and voluntary assumption of risk, make it difficult to use this principle as a basis for allocation: it is rather a constraint on efficiency and efficacy as the sole criteria. The principle of equality might require foregoing the development of a technology that would restrict equal access to, an expensive, life saving procedure such as dialysis or cardiac transplantation. This is ethically acceptable only if it excludes entire classes from treatment on the basis of categories of disease. If this were done, as Outka suggests, it would be important to consider such criteria as the pain and suffering various diseases involve, their costs, and the ages in life when they are likely to occur. Finally, the principle of liberty is a moral principle of great importance, not easily overridden. It imposes major limitations on efforts to promote prevention and makes it likely that acute care, even for problems that could be avoided by the voluntary choice of individuals, will need to be provided (Childress 1981).

Daniels is the first philosopher to present a comprehensive theory of justice for health care. In his unpublished manuscript, Just Health Care, be urges "the fair equality of opportunity principle as an appropriate principle to govern macroallocation decisions about the design of our health care system. Such a principle defines, from the perspective of justice, what the moral function of the health care system must be--to help guarantee fair equality of opportunity"

(Daniels 1984, p. 74). Health care has as its purpose the protection and promotion of "normal species functioning." This refers to the fullfillment of those needs which are present to human beings during the entire course of their lives, independent of any particular choices and life plans, but without which particular choices and life plans cannot be carried out. The normal opportunity range for a given society is the "array of life plans reasonable persons in it are likely to consider for themselves" (p. 55). This range is dependent on facts about the society. Equality of opportunity means that an individual faces no obstacles to pursuing life plans within the normal range that is appropriate to his talents and skills. Disease and disability undercut the range of opportunities that would be open to individual, and health care acquires to special moral importance from its ability to protect the individual's fair share of that normal range of opportunity. If protecting fair equality of opportunity is a general principle of justice that ought to govern institutions in a society, then it ought to govern health care institutions as well.

In light of this thesis, Daniels maintains that individuals are entitled to have certain needs met. These entitlements are specified only indirectly, as a result of the basic health care institutions acting in accord with the general principles governing opportunity. Deciding which needs are to be met and which resources are to be devoted to meeting them requires careful moral judgment and a wealth of empirical knowledge about the effects of alternative allocations. The various institutions that effect opportunity must be weighed against what is needed to provide for other important social

institutions. "Clearly," he states, "health care institutions capable of protecting opportunity can be maintained only in societies whose productive capacities they do not undermine" (p. 91).

The President's Commission responded to the Congressional mandate to study the ethical and legal implications of differences in availability in health care by concluding that "society has an ethical obligation to ensure equitable access to an adequate level of health care without the imposition of excessive burdens" (President's Commission 1983, p. 4). It argued that this obligation rested on the special importance of health care in relieving suffering, preventing premature death, restoring functioning, increasing opportunity, providing information about an individual's health condition, and giving evidence of mutual empathy and compassion.

The Commission explains that "equitable access" refers to access to an adequate level of care. It does not refer to equality, in the sense that every person receives an equal share of the health care dollar or is provided with the same level of health care. It does not refer to access solely according to individual benefit or individual need. Each of these alternative definitions of equitable access has unacceptable implications. The first interferes with the liberty of individuals to use their personal resources to promote the goods they prefer; the second neglects the costs that an unlimited response to personal choices imposes upon others and upon other social needs. Thus, the Commission neglects access to an <u>adequate</u> level of care as its specification of equity of access.

Adequate is defined as that level of care that will enable individuals to achieve sufficient welfare, opportunity, information, and evidence of interpersonal concern to facilitate a reasonably full and satisfying life. Also, equitable access must be free of excessive burdens for the individuals seeking care: burdens in expenditure of significant resources, inconvenience, time, etc. Recognizing that the concept of adequacy is indefinite, the Commission refrains from the impossible task of specifying what adequate care should include; it suggests characteristics of adequacy that deserve attention in any discussion of an equitable health policy. These characteristics are the relationship between various forms of care and the health needs of an individual, and the relationship between the benefits of care and its costs, including diversion of resources from other socially desirable endeavors. The Commission concludes:

> Consequently, the level of care deemed adequate should reflect a reasoned judgment not only about impact of the condition on the welfare and opportunity of the individual but also about the efficacy and the costs of the care itself in relation to other conditions and the efficacy and cost of the care that is available for them...and the cost of each proposed option in terms of foregone opportunities to apply the same resources to social goals other than that of ensuring access (to health care) (p. 36-37).

The reasoned judgment is made by drawing upon such criteria as professional expertise, average current use of health resources, lists of services deemed necessary, etc. It recognizes the extreme complexity of the problems posed by the principle of ensuring equity of access and recommends a variety of means to resolve these problems: better data and analysis of health care needs and the costs

and efficacy of forms of care, education of professionals and the public, and various financial strategies to limit and distribute costs.

The President's Commission formed its statement on justice in health care after consulting leading scholars in health policy, health law, and health economics. It asked several moral philosophers to analyze carefully the various theories of justice for their relevance to this issue. (Wikler 1983; Sass 1983) It did not rely on any one theory or one philosophical formulation, but preferred to rest its case on mutiple moral considerations. We will note the important points made by several of these contributors to the Commission's work.

Gibbard provided an exhaustive analysis of distributive justice in light of the "prospective pareto principle." The Pareto Principle, familiar to students of price theory or social choice theory in economics, states that a condition is efficient whenever it is impossible to change it so as to make at least one person better off without at the same time making at least one person worse off. Gibbard interprets this principle as a moral principle and, after careful analysis, comes to these conclusions:

> It follows from the principle that except under special circumstances, there is no moral right to equal availability of health care, unless there is a moral right to full economic equality in general. It follows that if a treatment is sufficiently expensive, it should be withheld even if it is the most effective treatment for a grave ailment (Gibbard 1983, p. 158).

Gibbard's first conclusion need not concern us here. His second conclusion is directly relevant to the question of cardiac transplantation. He supports it by an argument familiar in decision

theory: the limits of rationality in accepting risks. Gibbard proposes an analogy to illustrate this argument. A person may choose to insure himself against the need for an extraordinarily expensive life saving treatment. His choice would be whether to accept the risk of needing this treatment and not being insured for it against the benefit of saving on the insurance premium to purchase some other desired good. If the chances of needing the treatment are small and the premium large, the risk of declining insurance may be rational. On the social level, an insurance scheme for an expensive form of medical care might be proposed. The cost would be distributed so that each person, prior to knowing whether he will need the care, fares worse given the scheme and his share in its costs than he would without the scheme, by keeping his share of the costs. In this case, says Gibbard, it is ethically better to not have the scheme. Of course, he remarks, applying this principle requires both extensive knowledge of life under various circumstances and careful reflection about the risks of taking various courses. Gibbard's argument is controversal. One consultant to this project was not persuaded by it. Another stated that he did not believe the conditions of rationality required by thej Parets Principle are fulfilled by decision makers in the real world. Yet Gibbard's argument does lead to a conclusion that conforms with all other commentators. He concludes:

> If the Prospective Pareto Principle is valid, then there is no defense for the universal precept, "where life is at stake, cost is no object." That precept may apply in specific circumstances, where the cost of the best treatment is moderate and the treatment is effective in

> saving life and restoring health....The Pareto Principle and considerations of rational prudence, however, tell us that the best known treatment for a serious ailment might not be worth the cost, ethically speaking . . . there are ways of allocating the economic burdens that are so onerous that it would be better, ethically speaking, for no one to receive certain kinds of life saving treatments, than for the burdens to be imposed and for everyone to be assured of getting those treatments if in need of them. [p.168-169] (p. 169).

A second consultant to the President's Commission, Gauthier, views the principles of justice as the outcome of deliberations between individuals representative of a society bargaining to secure the greatest benefit for each participant. The bargainers do not get all they want as individuals, but the society delivers more to individuals than they would have received without cooperation. Gathier argues that two features about health care are morally relevant: need is unequal from person to person and health is "accidental" in the sense that it is not part of one's personal identity. These two features require a means of distribution other than the free market. The bargainers who, in ordinary circumstances, can bargain to obtain the fruits of the exercise of their individual talents and to fulfill their individual needs, must refrain from this in bargaining about health resources. Gauthier asserts that this abstraction from personal needs will lead rational bargainers to adopt a cost effective criterion for distribution of health care: they will seek to assure the maximum health per dollar. Since they have no special knowledge of their individual health needs, they will choose to insure themselves for cheap, effective health services rather than expensive services of doubtful effectiveness, under conditions of scarcity. Gauthier

suggests that the availability of different insurance packages, together with subsidization of those with substandard resources provides the most just form of allocation of resources. He concludes:

> It is unfair to provide expensive health services however much we would like to do so, if less costly services, whether in health or other areas, affording greater utility for a given expenditure must be sacrificed ... fair access is comprehensive access within the limits set by considerations of cost effectiveness...Fair access, since it is related to remedial and compensatory measures for deviations from natural human functioning, is directed primarily at enabling persons to live normal life spans under conditions that enable them to form and pursue reasonable life plans reflecting their talents, aptitudes, and interests ... (and) efforts to extend life may involve excessive drain on limited resources ... the claim of health care needs is the claim that a reasonable and impartial individual, fairly situated in his or her access to resources, would choose to recognize (Gauthier 1983, p. 204-205).

C. PRINCIPLES OTHER THAN JUSTICE GOVERNING ALLOCATION OF RESOURCES

The allocation of scarce resources has usually been discussed by philosophers as a problem of justice. However, other moral principles, alone or in combination with the principle of justice, may be thought to provide compelling arguments about allocation of resources in a society. Some of these might be the principles of liberty, of beneficence, of respect, of charity, of obligation toward the elderly, or of concern for future generations. Few of these ideas have been explored carefully by the philosophers who have written about the allocation of health care resources. The principle of liberty is a modest exception: several authors have espoused a libertarian principle and suggested how it might pertain to health care (Nozick 1974). However, even here, the development of this idea is meager.

The libertarian principle contends that coercion may be ethically employed in society only to prevent or punish physical harm, theft, or fraud, and to enforce contracts. Coercive measures cannot be used to distribute social goods. Libertarians favor a free market in medical services, even though it may produce serious inequalities. From this viewpoint, expensive medical interventions can be available to those who can and wish to purchase them. Private beneficence and charity urge assistance to the needy; justice does not. Most ethicists reject this thorough reliance on the free market (Wikler 1983, p. 124-129).

One author, Buchanan, proposes that, even if one adopts the libertarian principle, it is possible to argue in favor of coercive measures to assure a decent minimum of health care in society. Indeed, he proposes that doing so allows a more precise specification of the content of the abstract and elusive term "decent minimum" than do the various justice arguments.

Buchanan begins with an assumption accepted even by the libertarians: there is a moral obligation of charity or beneficence to those in need. In addition, the libertarian will be concerned about the efficacy of charity: voluntary contributions should reach those who need them and do them the intended good. Buchanan then recalls one of the "paradoxes of rationality," namely, that individuals moved by charity to contribute to the needy may refrain from doing so unless they are assured that their contribution will make a difference. They must know that others will give so that a sum sufficient to produce the needed benefit is accumulated. Thus, even for the libertarian, a coercive system of contribution is necessary to

effect the fulfillment of the principle of beneficence. This would specify certain health programs for the needy and require those who possess resources to contribute to such programs, usually through taxation. "This would coordinate charitable efforts by focusing them on one set of services among the indefinitely large constellation of possible expressions of beneficence and would assure that the decision to allocate resources to those services will become effective" (Buchanan 1983, p. 234).

Such a system also allows some specification of the "decent minimum." Decent minimum is capable of being defined by a criterion or by a list. The few criteria proposed are very vague, such as "Some conceptions of what constitutes a tolerable life in general" (Fried 1962, p. 32). Lists such as Enthoven's (Enthoven 1980) are indeterminate, providing no rule about what should be included or omitted, other than costlines (Daniels 1983). Justice arguments all conclude that there is a right to such a "decent minimum"; however, none of these arguments can specify what that minimum is before the outcome of empirical research or political process. This, says Buchanan, is an embarrassment to those who argue for a rights in justice approach, since "we often think of rights as rather sharply defined" (Buchanan 1983, p. 235). However, duties of beneficence are thought of as "imperfect duties," i.e., by their very nature they are not precisely delineated and allow persons discretion to decide not only how much to give but to whom they should give. On a social level, the character and scope of services to be provided are matters of discretion. Limits can be set without any injustice being done. Decisions to

provide more than the limit are matters of supererogation.

All that is needed to assure justice is a fair procedure for reaching a social decision on which set of services to provide. Buchanan concludes:

> We explored an argument for an enforceable decent minimum based not on a principle of justice, but upon the requirements of collective efforts for the fulfillment of moral obligations of charity or beneficence...when the enforced beneficence argument is combined with familiar prudential arguments, including arguments for traditional public health measures ... the result is a compelling case for creating an extensive set of legal entitlements to health care even in the absence of a universal moral right to health care (p. 238).

Other moral principles that might be supposed relevant to decisions about allocation provide, on brief examination, little help. Yet they may still be of some weight in formulating policy. Childress, for example, mentions the symbolic value of saving individual lives, exemplified in the End Stage Renal Disease Program. Childress suggest, that this symbolic value "reveals the virtue and character of its society and its members." In this light, allocation policies "may be thought of as ways for the society to define and to express its sense of itself, its values and its integrity." Yet he concludes, "this...has a strong appeal, and no doubt influences many of our decisions, but it is difficult to determine how much weight it should have in our policy decisions" (Childress 1981, p. 144).

The same criticism can be made of appeals to "humanity," "respect," "compassion." These are important virtues in members of the society and, undoubtedly, in the aggregate, make for a good

society. However, they are too general in meaning and too personal in reference to be used to justify allocation policies. Only in conjunction with principles that represent what Rawls calls "the virtues of social institutions" can they carry much weight. Thus, justice, equality and other principles of social cooperation remain the major sources of justification regarding allocation decisions.

Two particularly difficult questions must be raised about allocation of health services. How are the elderly to be treated in any allocation plan? Is there any special obligation to future generations? The elderly absorb a very large share of health resources, yet the return in terms of restoration of health and extension of life is, from many points of view, relatively small. Is it morally requisite to provide health resources to the elderly equal to those provided to younger persons? Is it morally opprobrious to single out the elderly (however "elderly" may be defined) as deserving less of the health resources of a society? Daniels is the sole author to attend carefully to this question. In his theory of just health care, he specifies that the central role of health care is maintenance of species typical functioning in order to support the normal opportunity range of individuals in a society. This claim needs a qualification because an individual's share of the normal range may vary with is stage of life or age. The principle of justice for health care thus requires that age-relative opportunity be protected for all people; this principle at once requires that appropriate health care be given to the elderly, but it leaves open the possibility that what is owed the elderly may be diffierent in kind or

even quantity from what is owed other age groups. Here prudence would guide justice: we must think of health care systems as institutions which distribute goods over our lifetimes, and we must design a prudent package of contingent benefits for each stage of our lives. This may mean taking from some stages to give more to others, or it may mean adjusting the type of health care most appropriate for each stage, but it does mean that we cannot ignore fair equality of opportunity for any stage. One consequence may be that life extending services may be less important in the late stages of life than those services, which, like personal care services, greatly enhance a frail, elderly person's share of the age-relative opportunity range [Daniels 1984, p.368]. Rationing by age-if it is part of a systematic, prudent allocation plan for society as a whole, and not merely a piecemeal use of age criteria - may be morally acceptable under certain constraints. But this point is not likely to justify age-rationing as a convenient cost-contained measure.

The question of obligations to future generations has received some attention in the general philosophical literature, but almost none of that attention has focused on the allocation of health care. In one of the rare essays on this topic, Green proposes the principle that "we are required to strive to ensure that our descendants are left with the means to a progressively better quality of life than ourselves and, at a very minimum, are not rendered worse off by our actions" (Green 1981, p. 198). He believes that this principle has many implications, the principle suggests caution in our commitments to certain forms of care. Pursuit of high technology care may lead us

to relinquish nearly all future discretionary income. This does not mean that programs like renal dialysis and artificial hearts are wrong, but that "major commitments to extensive curative or palliative efforts must be scrutinized for their sustainability into the future as well as their compatibility with other future commitments we would like to make toward health" (p. 200).

Philosophical authors are sensitive to the charge that they speak always about ideal worlds, rather than contingent reality. The philosophers who write about allocation of health resources take pains to clarify that they are aware of the "bottomless pit" problem: health care needs and desires can put enormous strains on an economy. Most of these authors would agree with Gutmann's remark, "I suspect that no philosophical argument can provide us with a cogent principle by which we an draw a line within the enormous group of goods that can improve health or extend the life prospects of individuals" (Gutmann 1983, p. 64). Still, the bottomless pit is, as Wikler points out, a philosophical problem. Any philosophical theory that identifies health care needs that require amelioration by society must explain why extreme needs can be justly ignored. Why should needs generate rights, Wikler asks, but only up to a point? Thus, most of the philosophical authors make some effort to acknowledge the need for certain limits. Few of them, with the exception of Daniels, attempt to provide a theoretical basis for these limits (Wikler 1983).

Gutmann, who declines to provide a theoretical limit, suggests a procedural rather than a substantive solution. She believes that a principle of equal access to health care establishes a criterion of

distribution for whatever level of health care a society provides for any of its members. Further philosophical argument might, she proposes, establish some criteria to judge when the publicly funded level of health care is so low as to be unfair to the least advantaged or so high as to create undue restrictions upon the ability of most people to live interesting and fulfilling lives. Then she states, "the remaining question of establishing a precise level of priorities among health care and other goods is appropriately left to the democratic decision-making...a democratic decision, the results of which are constrained by the principle of equal access, will give a relatively accurate reading of what most people believe to be an adequate level of health care protection" (p. 65). This democratic decision will bind even those who might want to purchase more than the socially mandated level of care. However, Gutmann admits that such a democratic decision is quite unlikely in our present society. "No democratic legislator could possibly succeed in winning support for a proposal that restricted market freedom as a strict interpretation of the equal access principle requires" (p. 65). Thus, it is necessary to provide a sufficiently high level of public health care for all citizens and a sufficiently elastic supply of health care in order to reduce the threat to universal provision of high quality care posed by a market in extra health care.

D. SUMMARY

This essay has reviewed the major contributions that ethicists have made to the public debate about the right to health care and the

just allocation of health care resources in society. These contributions take a variety of theoretical approaches and offer a multiplicity of arguments; however, they reach a similar set of conclusions. First, it is generally agreed that health constitutes a special good for individuals and society. It is also recognized that health is an extremely complex notion and refers to a wide range of human conditions. It is acknowledged that health care has only an indirect relationship to health. Thus, the philosophers almost inevitably distinguish among the moral claim to health, to health care, and to access to health care. The first claim is of little importance because health, as such, is beyond reach by human activity; the second is too complex to realize. The third, access to health care, can be the object of a moral claim.

Philosophers then go on to propose a theoretical justification for a moral claim to access. Almost all have chosen some formulation of the theory of justice. Before analyzing theories of justice, many philosophers are at pains to reject the suitability of the "rights" approach. This rejection arises from their awareness that the notion of rights would require dedication of unlimited resources to the health benefits of individuals that claiming such a right, and would rule out priority comparison between various sorts of health goods as well as goods of different sorts. It is too strong a claim. It is important to note that this rejection implies that philosophers would repudiate the proposal that any particular health care intervention, such as cardiac transplant, must be provided as a matter of right to

every individual needing such an intervention, even if the intervention is life-saving.

Philosophers do acknowledge that a right to access can be established within a theory of justice. (It is a philosophical commomplace that the term "rights" can stand for the moral claims of individuals prior to social considerations or, as here, to the conclusions of arguments about justice). Starting from different definitions of social or distributive justice, all philosophers who have examined the question (with the exception of libertarians) have concluded that all persons in a society have a right in justice to some level of access to health care. Some form of state or social intervention is needed to assure access to a just level. The level is expressed in various ways: the amount needed to provide a level of health equal to other persons' health, (Veatch 1976), a decent minimum (Fried and Buchanan), an adequate level (President's Commission). All these authors affirm that some forms of care could be eliminated from the level to which all have a right, if that form endangered the ability of the society to provide all a "decent" or "adequate" level.

At the same time, philosophers seldom affirm that some form of health care that might not be included in the adequate or decent level should not be available to those who might choose to purchase it. Several have considered and approved of insurance schemes that would allow persons to expend personal resources on more expensive forms of care, in accord with their own determination of acceptable risk. Philosophers have not examined closely the practical problems of the coexistence of a socially supported level of adequate care and a free

market in health care. However, many of them recognize the desirability of a "one tiered" system as the best realization of an ethical principle of equal access (Gutmann 1983).

Thus, on the basis of the philosopher's arguments, it can be asserted that an expensive procedure, such as cardiac transplantation, might or might not be included within the forms of care considered necessary to a decent minimum or adequacy. Its acceptability depends on the impact it would have on the assured provision of the adequate level of care for all citizens. The fact that it is life saving or life extending is not the most salient or weighty feature in favor of its inclusion in public supported programs.

Philosophers have not analyzed extensively the second important issue of just allocation of health care: the proportion of resources to be expended on health care in relation to resources to be spent on other social goods. Almost all, however, affirm that the expense of health care cannot be allowed to jeopardize other social institutions that are equally vital for a good society and the realization of personal goals. Still, this question may quite rightly be, as Paul Ramsey once noted, "almost, if not altogether incorrigible to moral reasoning and to rational determination" (Ramsey 1970, p. 240).

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